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STRENGTHENING FOOD SAFETY LAWS

HEARING

OF THE

COMMITTEE ON LABOR AND HUMAN RESOURCES UNITED STATES SENATE

ONE HUNDRED FIRST CONGRESS

FIRST SESSION

ON

EXAMINING THE ADMINISTRATION'S PROPOSED LEGISLATION ON THE VARIOUS FOOD SAFETY ISSUES

NOVEMBER 1, 1989

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STRENGTHENING FOOD SAFETY LAWS

WEDNESDAY, NOVEMBER 1, 1989

U.S. SENATE,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, DC.

The committee met, pursuant to notice, at 11:45 a.m., in room SD-430, Dirksen Senate Office Building, Senator Edward M. Kennedy (chairman of the committee) presiding.

Present: Senators Kennedy, Adams, and Hatch.

OPENING STATEMENT OF SENATOR KENNEDY

The CHAIRMAN. The committee will come to order.

I apologize at the outset to our witnesses for the late start of the hearing. We just completed a markup with an extremely important agenda, which delayed us to some extent, and the vote that we just had did as well.

I'll put my statement in the record.

These hearings today and next Tuesday have been called in response to the administration's proposal on the various food safety issues, and it was the intention of myself and the other members of the committee through both of these hearings, to receive testimony from those who have given this issue a good deal of time and attention.

At the conclusion of the earlier hearing, I outlined what I considered to be the central issues which are involved, and I do the same in my opening statement today. We'll move to the witnesses at this time.

[The prepared statements of Senators Kennedy, Adams and Hatch follow:]

PREPARED STATEMENT OF SENATOR KENNEDY

The CHAIRMAN. Americans across the Nation are increasingly concerned about the safety of the food we consume. the Alar scare on apples raised serious questions about the use of cancer causing pesticides in agriculture. The Chilean grape scare raised similar questions about the competence of food inspection by the Federal Government. These incidents are only the tip of the iceberg. The public is uneasy. It is clear that Congress and the Administration are doing too little to assure the safety of the fruits, vegetables, meats, and fish that we eat.

Pesticides and other chemicals are commonly used by farmers to protect crops from infestation. We know that these chemicals have dramatically improved crop yield and productivity, but we know

much less about the risk to the public health. In response to the growing concerns among consumers about the safety of pesticides, many small, family farmers have adopted alternative, low pesticide techniques. Organic agriculture methods are growing in popularity as consumers demand produce and other food products that are free from pesticide and other chemical residues. But most large, corporate agriculture businesses continue to use large quantities of pesticides, seeking to maximize crop yields at any expense to public health and safety.

The two Federal agencies charged with assuring the safety of the food supply and protecting the public health, the Environmental Protection Agency and the Food and Drug Administration, permit the use of these threatening chemicals. To respond to the real and justifiable concerns about the dangers of such use, we need to strengthen the authority of these agencies to limit pesticide and other chemical residues on foods and ensure that their use is safe.

Reports from Government and the private sector underscore the public's concern. In 1987, the National Academy of Sciences reported that legal applications of 28 different pesticides could lead to cancer for up to 6 of every 1,000 people exposed. The Environmental Protection Agency has identified at lease 25 other carcinogenic pesticides legally used on food.

As these reports make clear, our current laws are not adequately protecting the public. Earlier this year, I introduced legislation to remedy these defects by strengthening Federal standards for residues on food.

Last week, the Administration offered similar proposals in this area as well. The president's recommendations contain excellent suggestions to enhance the ability of the Environmental Protection Agency to remove dangerous pesticides from the market. Unfortunately, the recommendations also significantly weaken Federal food safety laws; even worse, the recommendations would prohibit States from enacting stricter standards on their own.

The Administration's proposals represent an unwarranted retreat on this critical environmental issue. We need stronger standards, to protect the safety of the public, not weaker standards to protect the profits of private industry.

Families deserve convincing assurances that all the fruits, vegetables and canned and processed foods they buy and eat are free from cancer-causing pesticides and chemicals. Congress has a responsibility to guarantee that the Nation's food supply is safe, and that the seal of Federal approval does not become a license to conceal carcinogens and other threats to public health.

Earlier this year, our committee held two hearings on the dangers of pesticide residues on foods. Since the Administration announced their food safety initiative, many chemical companies, agricultural and consumer groups, have provided us with their comments and criticisms on issues relating to pesticide residues on foods.

During today's hearing, we will receive testimony representing both the consumer and industry perspectives. Within the next few days, we hope to hear from representatives from the FDA, EPA and the Department of Agriculture, with a view to final committee action on legislation before the end of this session.

Food safety is a critical issue, and Congress must respond. We have the finest agricultural and food production system in the world. There is no reason it cannot also produce the safest food supply in the world.

Senator Adams

PREPARED STATEMENT OF SENATOR ADAMS

Senator ADAMS. Mr. Chairman, let me begin by thanking you for holding these hearings. I am aware of your interest in keeping this legislation on a fast track. This legislation, however, will impact many people in my State, both farmers and consumers; and I deeply appreciate your courtesy in giving us a chance to examine this legislation in more detail.

I am very troubled, Mr. Chairman, by the current state of affairs regarding Federal regulation of the use of pesticides in our food supply. Right now our policy seems designed to cause the maximum pain to farmers and consumers alike.

Consumers hear claims that various products are unsafe, and they do not know who to believe. If the Alar scare taught us anything, it is that consumers do not rust the regulatory process to ensure that the food they feed their children is safe.

Farmers are also at risk. Chemicals they have used for years are suddenly assailed as unsafe, and they take an economic beating in the market place. Apple growers in my State, most of whom no longer used Alar, have suffered greatly this year. I want to make sure that doesn't happen again.

The Alar scare was an example of what should be a scientific issue—is a chemical safe—becoming a market issue. Once it became a market issue, everybody lost. Consumers stopped buying apples and apple products, and lost access to one of nature's most nutritionally valuable foods. Farmers lost income they couldn't afford to lose. It is time to get this issue out of the media and back in the laboratory where it belongs.

For that to happen, we must have a regulatory system we can trust. My trust in the current Administration, unfortunately, is very low.

Look at what we have just gone through with Red Dye #3. The FDA, after studying the issue for nearly a quarter of a century, told the agricultural industry that the law required them to terminate provisional listing of this dye. It also said that as far as they were concerned the dye was safe, and encouraged the industry to ask Congress to reverse the FDA's action. Congressional attempts to do so, which I opposed, are bogged down in the Agriculture Appropriations Conference Committee.

This incredibly cynical performance is exactly the kind of thing that has resulted in the loss of consumer confidence. I don't think the FDA is helping growers in my State when they pull this kind of stunt. It hurts, because it perpetuates the impression that they system is rigged, and that consumers better look elsewhere for reliable information.

The question of how much we trust this administration, and this EPA is also going to influence our action on the bill. The bill sets a single negligible risk standard for setting tolerances for pesticide

residues in food. Everyone probably agrees that this is a good idea. The key question for us is do we give the agency flexibility in setting the standard, or do we essentially do it ourselves?

I don't know the answer to this question. On the one hand, I think our goal should be to as accurately as possible answer the question—is this product safe? This means taking into account local factors like climate and application techniques, and is an argument in favor of giving the agency the flexibility to respond to specific circumstances. On the other hand, if we give the agency flexibility, can we trust them not to abuse that flexibility, and avoid the tough decisions that will inevitably result in some pain to agriculture?

I don't know. The bill before us doesn't trust the agency, and restricts its discretion as much as possible. I wish I could say such suspicion was unwarranted, but I can't

In conclusion, Mr. chairman, I look forward to hearing what these witnesses have to say today. Hopefully we will hear creative suggestions for getting us out of the mess we're in right now.

Thank you.

PREPARED OPENING STATEMENT OF SENATOR HATCH

Senator HATCH. Mr. Chairman, I appreciate your keen interest in correcting our Federal food safety laws so that we can protect American consumers from Adverse health effects. This has been an interest of mine for almost a decade, and I applaud your determination to see that this committee act in a timely manner to implement changes in our laws, including those recommended by President Bush on Thursday, October 26, 1989.

While I am delighted to discuss these issues, I must invoke propriety into this process. Members of this committee were informed of today's hearing less than 48 hours ago. In light of that, there was insufficient time to prepared, to call witnesses, and to review written testimony in advance. Therefore, I have a letter signed by all Republican members of the committee requesting a minority day of hearings on food safety issues. Mr. Chairman, there is a great interest by every member of this committee in this issue. We want to work in a bipartisan manner to change our Federal food safety laws.

The American consumers want to know that our food supply is safe. I believe there are two pillars that must be constructed to restore consumer confidence. First, we must establish a strict and uniform food safety standard that is based on sound science in ensuring that our products can only pose a negligible risk of harm. Our current law, which utilizes a "zero-risk" standard, is no longer scientifically feasible. Further, this Delaney paradox is working to keep safer products off the market which could replace older, less safe products. Every Commissioner of the Food and Drug Administration for the past 29 years has called on Congress to remove the rigidity of the Delaney clause. Those are scientists appointed by Presidents of both parties who recognize that we must have workable, scientifically accurate Federal laws in order to protect the safety and health of American consumers.

The second pillar we must construct is to pass stronger enforcement laws that allow the removal of unsafe products with prudent dispatch. Our current system requires a process which takes 4 to 8 years before a product can be suspended or canceled for use. That is too long, and it is not surprising that States have undertaken efforts to protect their citizens when our Federal laws are so erratic. Rather, we need a strict and uniform food safety standard with strong enforcement tools so that we protect citizens in Utah as well as citizens in New York

I look forward to working with members of this committee to begin a dramatic effort to revise our outdated and unscientific Federal food safety laws. It will be challenging, it will require great courage, yet it will result in a safer food supply.

The CHAIRMAN. We have Janet Hathaway, Senior Attorney at the Natural Resources Defense Council; Anne Bloom, Staff Attorney at Public Citizen, and Edward Groth, the Associate Technical Director, Policy and Public Service, Consumers Union.

We'll start with Janet.

STATEMENTS OF JANET S. HATHAWAY, SENIOR ATTORNEY, NATURAL RESOURCES DEFENSE COUNCIL, WASHINGTON, DC; ANNE W. BLOOM, STAFF ATTORNEY, PUBLIC CITIZEN, WASHINGTON, DC, ACCOMPANIED BY WILLIAM SCHULTZ, STAFF ATTORNEY; AND EDWARD GROTH, III, PH.D., ASSOCIATE TECHNICAL DIRECTOR, POLICY AND PUBLIC SERVICE, CONSUMERS UNION, MOUNT VERNON, NY

Ms. HATHAWAY. Thank you, Mr. Chairman, for the opportunity to testify before this committee about President 'Bush's proposal to modify the pesticide laws and about S. 722, your Food Safety Amendments of 1989.

I have prepared a lengthy written statement that I hope to be included in the record, but I'd like to summarize.

The CHAIRMAN. The statements of all the witnesses will be included as if read, and we'll ask them all to summarize.

Ms. HATHAWAY. Thank you.

I am Janet Hathaway, Senior Project Attorney with NRDC. NRDC is a nonprofit organization of attorneys and scientists dedicated to protecting public health and the environment. Last week President Bush announced a plan to modify the Federal pesticide and food laws to address public concerns about pesticides in food. NRDC concludes that the Bush plan must be opposed as a cynical effort to deflect attention away from true food safety legislation such as the chairman's bill, S. 722.

The administration's response to the public outrage about Alar and other pesticides in our food is to propose a measure which cannot assure greater food safety, predictability or rationality in the regulation of pesticides.

The plan involves some minor improvements in EPA procedures which the agency could use to expedite the removal of some dangerous pesticides, but the proposal also fundamentally erodes the basic health protective standard of the food safety law and eliminates the powers of the States to protect their citizens.

The President's proposal includes a provision which could assist an aggressive EPA in removing especially dangerous pesticides from the market. I won't go into detail on that, but it is a small step in the right direction. But the Bush plan is a story of one step forward and two steps back. The President has proposed a major modification of the Federal Food, Drug and Cosmetic Act which would eliminate one of the central protections of that law, the Delaney clause, and replace it with greater discretion for the agency in setting pesticide residue limits or tolerances.

The President has characterized his proposal as negligible risk. But the more accurate description is on beyond negligible risk. The plan would automatically condone the use of pesticides which EPA declares to pose a cancer risk less than 10 in 1 million. This is a major retreat from only last year when the agency suggested it would consider cancer risks negligible only if they were under 1 in a million.

It seems highly cynical that in the wake of the Alar controversy, when consumers have demanded the government act to reduce carcinogenic risk in food, that the administration would instead raise ten-fold the cancer risk that would routinely be condoned.

Worst of all, the President's plan would enable EPA to permit the agricultural use of pesticides even when they pose a significant risk by EPA's admission. All that is needed is for the agency to state that the pesticide has sufficient benefits. The proposal authorizes the agency to look at any number of factors, including economic benefits to growers, to justify the continued use of pesticides that cause cancer, cause birth defects and other grave human health hazards.

The administration is willing to set no upper limit on how much risk it will condone by claiming that pesticides present some benefit to society.

The President's plan would also eliminate the States 'powers to set more stringent pesticide tolerances. The administration euphemistically refers to this portion of the plan as uniformity. But it is nothing but preemption of the State's fundamental right to protect its citizens. Although the administration characterizes this provision as needed to avoid "real concern to the food distribution industry and confusion to consumers," the real motivation is to ensure that Federal pesticide tolerances are invulnerable from State challenges. The States have seldom used their power to set more stringent pesticide tolerances, and only in the cases where the Federal Government has fundamentally failed to protect the food supply.

States did act to protect the public from ethylene dibromide and Alar, but only after extensive efforts to prod the Federal Government went unheeded. If the inherent power of States to protect citizens is abridged, as the President would propose to do, the consequence will be to insulate Federal pesticide decisions from a legitimate scientific debate with State health experts. Consumer confidence will be further eroded.

The Grocery Manufacturers Association and the National Agricultural Chemicals Association have long sought congressional action to preempt State tolerance-setting authority, but even the Reagan Administration refused to endorse this controversial proposal. Ironically, it is the self-proclaimed environmental President

who is willing to roll back State public health powers in the service of the chemical and food industry.

Finally, I would like to sum up. The so-called negligible risk standard and the uniformity proposals both are insidiously designed to weaken the current law and deceive the public. The Bush plan would gut the current food safety laws' purely health-based standards and replace them with virtually unlimited discretion for EPA.

The proposal is not designed to reduce pesticides risks at all but instead designed to shield the agency from scrutiny and challenge. This is not a food safety initiative, it is a justify-significant-pesticide-risk plan. The Bush proposal should be denounced as a retreat from food safety disguised as a proposal to address public fears from pesticide risks.

Thank you.

[The prepared statement of Ms. Hathaway follows:]

PREPARED STATEMENT OF JANET S. HATHAWAY

Thank you for the opportunity to testify before this Committee about President Bush's recently announced proposal to modify the pesticide laws and S.722, the Food Safety Amendments of 1989. I am Janet Hathaway, senior project attorney with NRDC. The Natural Resources Defense Council (NRDC) is a non-profit organization of attorneys and scientists dedicated to protecting public health and the environment.

NRDC has recently released a study, "Intolerable Risk: Pesticides in our Children's Food"[1], which documents that the risks from actual residue levels of 23 pesticides used in 27 fruits and vegetables greatly exceed even the government's own standards for acceptable risk. In the decade NRDC has been working to improve pesticide policy, NRDC released a book entitled Pesticide Alert[2], presented testimony before this and other Congressional committees, and issued numerous reports documenting serious flaws in our regulations and laws concerning pesticides.[3] NRDC was also centrally involved in the effort to reform the regulation of pesticides under the Federal

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[1] B. Sewell, R. Whyatt, J. Hathaway and L. Mott; "Intolerable Risk: Pesticides in our Children's Food," Natural Resources Defense Council, February 1989.

[2] Lawrie Mott and Karen Snyder, Natural Resources Defense Council, Pesticide Alert: A Guide to Pesticides in Fruits and Vegetables, 1988.

[3] Hearne, S., "Harvest of Unknowns: Pesticide Contamination in Imported Foods," NRDC, 1984; Mott, L. and Broad, M., "Pesticides in Food: What the Public Needs to Know," NRDC, March 15, 1984; Mott, L., "Pesticide Reregistration: An Evaluation of EPA's Progress," NRDC, April 3, 1986.

Insecticide, Fungicide and Rodenticide Act (FIFRA). Some key elements of the reform proposals advanced by NRDC were included in legislation the Congress enacted last year.[4] We have also sought improvements to the Federal Food, Drug and Cosmetic Act (FFDCA), the law that governs pesticide residues in food.

I. PRESIDENT BUSH'S PESTICIDE PROPOSAL WILL NOT ENSURE GREATER HEALTH PROTECTION FROM PESTICIDES IN FOOD.

Last week, President Bush announced a plan to modify the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) to address public concerns about pesticides in food. NRDC concludes that the Bush plan must be opposed as a cynical effort to deflect attention away from true food safety legislation such as the Chairman's bill, S.722. The Administration's response to the public outrage about Alar and other pesticides is a measure which cannot assure greater safety, predictability or rationality in the regulation of pesticides. The plan involves some minor improvements in EPA procedures which the Agency could use to expedite the removal of some dangerous pesticides from the market. But the Administration's pesticide proposal also fundamentally erodes the basic health-protective standard in the food safety law and eliminates essential powers of states to protect their citizens.

The Administration should be aware that the lesson to be

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[4] Federal Insecticide, Fungicide and Rodenticide Act Amendments of 1988, Pub. L. 100-532, October 25, 1988.

learned from the Alar controversy is not to condescendingly attempt to placate the public; the solution is a rigorous plan which would ensure rapid and dramatic reductions in the use of dangerous pesticides, such as the reforms envisioned by the authors of S.722. NRDC strongly opposes the Bush proposal, because it purports to solve our problems with dangerous pesticides in food without demonstrating any commitment to risk reduction.

A. THE ADMINISTRATION PLAN CONTAINS MODEST IMPROVEMENTS TO THE FIFRA, WHICH COULD RESULT IN SWIFTER CANCELLATIONS AND MORE SUSPENSION OF ESPECIALLY DANGEROUS PESTICIDES.

The Administration plan contains provisions which may improve the process of removing pesticides EPA identifies as highly hazardous from the market. The proposal would potentially reduce the time taken to cancel pesticides under FIFRA by eliminating the opportunity for a cumbersome, formal adjudicatory hearing within the Agency prior to judicial review. According to a House Agriculture Committee report, the period of time EPA takes to cancel pesticides averages about 5 years, but the total amount of delay during the formal cancellation hearings since 1977 "is a minor portion of the total time spent in review and cancellation of a pesticide."[5] The Agriculture Committee estimated that cancellation hearings "are infrequently used" and are responsible for only 8% of the lengthy period the Agency

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[5] House Agriculture Committee, Staff Memo on Special Review/Cancellation Legislation, made part of the hearing record of the Department Operations, Research and Foreign Agriculture Subcommittee concerning H.R. 3292, October 19, 1989, p. 2.

takes to remove pesticides from the market.[6] Therefore, while it is certainly advisable to streamline the byzantine pesticide cancellation process, the Administration proposal would only slightly accelerate cancellation.

Under FIFRA, EPA must declare a pesticide an "imminent hazard" in order to immediately suspend its sale and use. The Administration's proposed changes in the definition of "imminent hazard" will clarify the Agency's authority to suspend pesticides which pose high chronic health risks and presumably remove some of EPA's historical reluctance to invoke the "imminent hazard" clause to remove dangerous pesticides from the market. EPA has only rarely--three times in the last seventeen years--used its power to suspend pesticides.[7] EPA cannot fairly be said to have tested the limits of its current authority to immediately remove pesticides from the market, but it has concluded that FIFRA's "high standard has prevented the Agency from taking timely action to remove pesticides from the marketplace. . . ."[8] While NRDC believes that statutory reform of the "imminent hazard" definition is unnecessary, given the wide discretion available to the Agency under the current law, we consider the President's clarification of the suspension power a minor improvement of the FIFRA. However, it is important for the Committee to recognize

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[6] Id. p. 2-3.

[7] EPA has suspended 2,4,5-T/Silvex, ethylene dibromide (EDB) and dinoseb.

[8] EPA/HHS/USDA, President Bush's Food Safety Plan: Standard for Suspension Fact Sheet, October 26, 1989.

that EPA's lethargy was not due to a lack of authority to suspend dangerous pesticides--it was due to a lack of political will. This proposal can enhance and clarify authorities, but it certainly cannot inject the EPA with resolve to remove dangerous pesticides from use in agriculture.

Included in the Bush proposal are proposals which could improve the government's woefully inadequate data on how and where pesticides are used and enhance the government's ability to penalize those who violate the law. Because enforcement is left primarily to the states, and because states' enforcement programs are chronically underfunded, this sensible proposal is unlikely to significantly change how pesticides are used.

The President's plan would also require--beginning 15 years from now--periodic review of newly registered pesticides, in order to ensure that these chemicals pass muster under evolving scientific standards. Periodic review is reasonable, but it will do nothing to improve our current level of protection from pesticides.

Finally, the President's plan would amend FIFRA to require earlier and apparently more extensive consultations with the United States Department of Agriculture and the Department of Health and Human Services before EPA could propose either to cancel or suspend a pesticide. These consultations would apparently be secret and excluded from the rule-making record. The plan explicitly shields these deliberations from judicial review. NRDC objects to this proposal. It could only serve to

delay and complicate an already glacial cancellation process. USDA and HHS are currently afforded a sufficient opportunity to comment on EPA plans to cancel or suspend pesticides. NRDC is concerned that this proposal would give USDA greater power to block the removal of pesticides from agricultural use, even when the pesticides' dangers are manifest.

B. THE PRESIDENT'S PLAN WOULD SUBSTANTIALLY WEAKEN THE FOOD LAW, TRANSFORMING IT FROM A HEALTH-BASED STATUTE TO A STATUTE WHICH JUSTIFIES HUMAN HEALTH HAZARDS ON THE BASIS OF ECONOMIC ANALYSES.

The President has proposed a major modification of the Federal Food, Drug and Cosmetic Act (FFDCA) which would eliminate some of the central protections of that law and replace them with greater discretion for the EPA in setting pesticide residue limits ("tolerances"). The President has characterized his proposal as "negligible risk" but the more accurate description is "on beyond negligible risk". The plan would automatically condone the use of pesticides which EPA believes pose a risk less than 10 in a million. This is a major retreat from only last year, when the Agency suggested that it would consider cancer risks "negligible" if they were under one in a million. It seems highly cynical that in the wake of the Alar controversy, when consumers have demanded that the government act to ensure the food supply bears less carcinogenic risk, the Administration would instead raise ten-fold the cancer risk that would be routinely condoned.

Nothing in the Administration's proposal ensures that children's risks would meet even the government's new lax

negligible risk standard. Here, too, the government refuses to heed the public's demand for food safe for all segments of our population, but particularly for our most vulnerable citizens--children. The Administration has refused to promise that all food-use pesticides will be regulated to ensure that they are safe for the most exposed, most vulnerable people in society.

The Administration's proposal also continues to defy reason by regulating pesticides as though people were exposed to only one chemical over a lifetime. The government is quite aware that several pesticides may be present on a single piece of fruit, and citizens normally consume dozens in the course of a week. But the government intends to continue to regulate pesticides without calculating the greatly increased risk which results from the multiplicity of residues we consume in our food. Until the EPA begins to limit our cumulative risk from pesticides in food, consumers will not--and should not--trust that our food is safe.

Worst of all, the President's plan will enable EPA to permit the agricultural use of pesticides which pose a significant risk--even by EPA's admission--whenever the Agency states that the pesticide has sufficient benefits. The proposal authorizes the Agency to look at a number of factors, including economic benefits to growers, in order to sanction the continued use of such hazardous pesticides. The Administration is willing to set no upper limit on how much risk it may condone by claiming that the pesticides are somehow beneficial.

The President's plan would eliminate the states' powers to set more stringent pesticide tolerances. The Administration euphemistically refers to this plan as "uniformity", but it is nothing but preemption of a state's right to protect its citizens. Although the Administration characterizes this provision as needed to avoid "real concern to the food distribution industry and . . . confusion to consumers"[9], the real motivation is to ensure that federal pesticide tolerances are invulnerable from state challenge.

The states have not used their power to set more stringent pesticide tolerances except where the federal government has fundamentally failed to protect the food supply.[10] States have acted to set more protective limits on ethylene dibromide (EDB) and Alar (daminozide) residues in food only after extensive efforts to prod the federal government went unheeded. If the inherent power of the states to protect their citizens is abridged, as the President would propose to do, the consequence would be to insulate the federal pesticide program from legitimate scientific debate. Consumer confidence in the federal program will suffer as the program as becomes less accountable.

Under the Bush plan, no matter how egregiously unsafe the federal standard, once the federal government reregisters a pesticide and sets a new standard, the federal standard will

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[9] The White House, Office of the Press Secretary, "Fact Sheet: President Bush's Food Safety Plan," October 26, 1989, page 9.

[10] See section VI-C, infra.

displace all other residue limits. There is simply no possible health or environmental protection purpose to be served by preempting the states. The Grocery Manufacturers Association and the National Agricultural Chemicals Association have sought Congressional action to preempt state tolerance-setting authority for many years, but even the Reagan Administration refused to endorse this controversial proposal. Ironically, it is the self-proclaimed "environmental President" who is willing to roll back states' public health powers in the service of the chemical and food industries.

The so-called "negligible risk" standard and the "uniformity" proposal both insidiously weaken current law and deceive the public. The Bush plan would gut the current food safety law's purely health-based standards, and replace them with virtually unlimited discretion for EPA. Moreover, the proposal is not designed to reduce pesticide risks at all, but is instead designed to shield the Agency from scrutiny and challenge. This is not a "food safety" initiative--it is a "justify significant pesticide risk" plan. The Bush proposal should be denounced as a retreat from food safety, cynically disguised as a proposal to address public fears about pesticide risks.

II. CURRENT LAW DOES NOT PROVIDE ADEQUATE PUBLIC HEALTH PROTECTION FROM PESTICIDES IN FOOD.

NRDC has identified many serious deficiencies in our federal program to protect the public from pesticides in food. Among the most fundamental are the following:

***EPA has incomplete or inadequate toxicological and residue chemistry data for many of the nearly 300 pesticide active ingredients used in or on food. The legal limits for residues of pesticides remaining in food (or "tolerances") were established for many pesticides before the Agency had information on the long-term effects of dietary exposure. When EPA receives new data on a pesticide's potential to cause cancer, birth defects, reproductive disorders, or other deleterious consequences, EPA does not rapidly reassess and revise tolerances to reflect the best available safety data.

***Ingredients which do not kill, repel or control pests, misleadingly termed "inert" ingredients, are not adequately regulated, although many may cause equally serious adverse effects as "active" ingredients.

***EPA lacks authority to act immediately to modify or revoke tolerances even when new information indicates an extreme risk to public health.

***EPA grants tolerances for pesticides even in the absence of a practical analytic method for measuring the residues in foods. The agencies which enforce tolerances, the Food and Drug Administration

(FDA) and the U.S. Department of Agriculture (USDA), are forced by their limited equipment and resources to rely almost exclusively on multi-residue analytical methods. The agencies are unable to detect nearly half of the pesticides for which EPA has set tolerances using multi-residue methods.

***EPA has interpreted the FFDCA to condone the presence of carcinogenic pesticides in raw food and in certain processed foods. EPA has argued that a risk-benefit analysis is appropriate for determining when carcinogenic pesticides can be used on raw foods.

***Although the FFDCA contains a provision--the "Delaney clause"--which prohibits the use of certain carcinogenic pesticides in food, EPA has invoked the Delaney clause infrequently and never with respect to pesticides which have been on the market for many years. Old pesticides pose some of the greatest dietary hazards, but EPA allows the continued, widespread use of old, carcinogenic pesticides in food.

S.722 is an important public health protection bill. It would correct the most serious defects in our current programs to control pesticide residues in food. The solutions offered by the bill fall short of the ideal. Most notably, S.722 does not eliminate all cancer-causing or otherwise dangerous pesticides from our food supply. However, the bill does require that such

pesticides must be used in a way which will ensure that residue levels pose relatively low risks. S.722 would markedly improve food safety and is urgently needed to restore the public's confidence in our food supply.

III. EPA HAS NOT ENFORCED THE DELANEY CLAUSE TO PROTECT THE PUBLIC FROM CARCINOGENIC PESTICIDE RESIDUES IN FOOD.

S.722 would eliminate the application of the Delaney clause to pesticides and require the EPA to instead apply a "negligible risk" standard to pesticides used in food. NRDC concludes that the application of the negligible risk standard of S.722 to all foods--whether raw or processed--would in fact improve food safety. This is so because the Delaney clause has limited application to pesticides in food, and because EPA has not enforced the Delaney clause even when by the terms of the FFDCA the clause should prohibit the use of a pesticide on certain foods.

People may assume that carcinogens in food are illegal, thanks to the Federal Food, Drug and Cosmetic Act's famous "Delaney clause". Unfortunately, this is not true. The Delaney clause does not even prohibit all carcinogenic pesticides in food. The Delaney clause only rules out the use of some cancer-causing pesticides (i.e., ones that concentrate during processing and ones used in post-harvest treatments) on some foods (processed foods). Moreover, even when Delaney clause does

apply, the agencies charged with its implementation have routinely ignored or cleverly side-stepped the restriction.[11]

Only twice in the three decades since Delaney became law has EPA invoked the clause to refuse a new food use of a carcinogenic pesticide.[12] Neither EPA nor FDA has ever cited the Delaney clause to justify banning an existing food use of a carcinogen since Congress overturned FDA's attempt to ban saccharin in 1977.[13]

The Federal Food, Drug and Cosmetic Act (FFDCA) includes two provisions which provide the authority for EPA to establish legal limits for pesticide residues in food ("tolerances") and for FDA to monitor and to enforce pesticide tolerances. Section 409,

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[11] Congress itself created some exclusions from the application of the Delaney clause, including the 1962 DES proviso and the clause exempting substances permitted as food additives before 1958 (the "prior sanction" exception). Numerous legally questionable exceptions to the Delaney clause have also been devised by the FDA, including the "sensitivity of method" (SOM) policy, "secondary mechanism" exception, the "constituents policy", and FDA's recently overruled "de minimis" interpretation. See National Academy of Sciences, Board on Agriculture, Regulating Pesticides in Food: The Delaney Paradox, 1987, hereinafter NAS, pp. 37-40; Richard A. Merrill, "FDA's Implementation of the Delaney Clause: Repudiation of Congressional Choice or Reasoned Adaptation to Scientific Progress?", 5 YALE J. ON REG. 21-29, 41-49 (1988); and Public Citizen v. Young, 831 F.2d 1108 (D.C. Cir. 1987).

[12] EPA cited the Delaney clause for its denial of tolerances for the pesticides fosetyl al and permethrin. NAS, supra, pp. 92-93. FDA invoked the Delaney clause only four times to prohibit the use of a substance in food. Merrill, supra, p. 9.

[13] Saccharin Study and Labeling Act, Pub. L. No. 95-203, 91 Stat. 1451 (1977).

including the Delaney clause[14], applies to food additives. Pesticides are considered food additives only when they occur in processed foods where cooking or other processing methods cause residues to concentrate above the legal limits for raw food.[15] Such concentration occurs in certain heat-processed foods such as applesauce, raisins and tomato paste. For processed foods with concentrated pesticide residues, the Delaney clause prohibits any pesticide "if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal. . . ."[16] Most commentators, including until recently both FDA and EPA, interpret the Delaney clause as a categorical prohibition on the use of cancer-causing substances within its scope. FDA's effort to re-interpret the Delaney clause to permit the use of color additives posing cancer risks less than one in a million through an implicit de minimis exception was rejected by the D.C. Circuit.[17]

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[14] In the Federal Food, Drug and Cosmetic Act, there are actually three Delaney clauses, one for each of three categories of substances--food additives, color additives, and animal drugs--which may leave residues in food. Pesticide residues are regulated by the food additives Delaney clause, which was added to the statute in 1958.

[15] FFDCA's definition of "food additive" excludes "pesticides on raw agricultural commodities." 21 U.S.C. § 321(s). Also exempted are processed foods "where the concentration of residue . . . is not greater than the tolerance prescribed for the raw agricultural commodity." Id. at § 402, 21 U.S.C. § 342(a)(2)(c).

[16] Federal Food, Drug and Cosmetic Act, § 409(c)(3), 21 U.S.C. § 348(c)(3).

[17] Public Citizen v. Young, 831 F.2d 1108, (D.C. Cir. 1987).

Many methods of food processing apparently reduce pesticide residues. For such processed foods and for raw foods, the products are legal if they comply with the provision of section 408. Section 408 reads:

> "The Administrator shall promulgate regulations establishing tolerances with respect to the use in or on raw agricultural commodities of poisonous or deleterious pesticide chemicals and of pesticide chemicals which are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of pesticide chemicals, as safe for use, to the extent necessary to protect the public health. In establishing any such regulation, the Administrator shall give appropriate consideration, among other relevant factors (1) to the necessity for the production of an adequate, wholesome, and economical food supply; (2) to the other ways in which the consumer may be affected by the same pesticide chemical or by other related substances that are poisonous or deleterious. . . ."[18]

Unfortunately, the meaning of this section is far from settled.

FDA interprets section 408 as permitting the use of carcinogens, so long as the risk from each individual chemical is not greater than 1×10^{-6}, or one cancer in a million persons exposed over a lifetime.[19] EPA reads the section 408 obligation to set pesticide tolerances "to the extent necessary to protect the public health" as granting the Agency broad discretion. EPA argues that section 408 is a risk-benefit standard, comparable to the standard for eliminating uses of pesticides under the Federal

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[18] FFDCA, § 408(b), 21 U.S.C. § 346(b) (1982), emphasis added.

[19] NAS, supra, p. 94.

Insecticide, Fungicide and Rodenticide Act (FIFRA).[20] The Agency believes that even levels of carcinogenic pesticides causing more than one cancer in the lifetime of one million exposed people can be lawful, so long as EPA identifies benefits which EPA determines "outweigh" the risks. Others, including public interest organizations, interpret section 408 to require EPA to limit pesticide residues to safe levels, and to prohibit all food uses of carcinogenic pesticides which pose risks at all detectible levels.[21]

EPA recently permitted the use of the carcinogenic pesticide permethrin on raw tomatoes, while outlawing the processing of permethrin-treated tomatoes into tomato paste. The Agency sidestepped a blatant violation of the Delaney clause by mandating that tomatoes treated with the carcinogen could not be processed into foods which would concentrate the pesticide residue. But the Agency's action failed to protect consumers from the carcinogenic pesticide in the raw tomatoes. EPA's interpretation of section 408 and the 409 Delaney clause has resulted in an anomalous situation: fresh fruits and vegetables--the foods many consumers believe to be healthiest--may be laced with pesticides which would be unlawful on cooked, dehydrated or otherwise processed foods.

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[20] Environmental Protection Agency, "Regulation of Pesticides in Food: Addressing the Delaney Paradox Policy Statement," October 19, 1988, 53 Federal Register 41104, at 41106.

[21] See Nader v. EPA, No. 87-7103, (9th Cir., filed June 18, 1987) [whether FFDCA § 408 should be read to prohibit all residues of the carcinogenic pesticide daminozide (Alar).]

But consumers will not necessarily avoid carcinogenic pesticides even if they somehow manage to eat only the processed foods in which residue concentration occurs. Carcinogenic pesticides including daminozide, benomyl, dicofol, chlorobenzilate and the EBDCs[22] (ethylenebidithiocarbamates) are known to concentrate in some processed foods, notwithstanding the Delaney prohibition. Although the Delaney clause unequivocally prohibits the use of these carcinogens, EPA and FDA have simply ignored these violations of the law. These chemicals were registered decades ago, before their cancer-causing properties were identified. The National Academy of Sciences reports that EPA has applied the Delaney clause almost exclusively to new pesticides. The Agency has virtually ignored the clause's application to pesticides registered before 1972.[23] Last month, NRDC joined with the state of California, Public Citizen and the AFL-CIO to challenge EPA's failure to eliminate the food uses of pesticides which EPA has identified as carcinogenic and concentrating in processed foods.[24]

The federal agencies routinely assure the public that the food supply is safe. But data supplied by the pesticide

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[22] The most widely-used class of synthetic fungicides, used in the U.S. and throughout the world on fruits and vegetables.

[23] NAS, supra, pp. 40-41.

[24] State of California, Public Citizen, Natural Resources Defense Council and AFL-CIO Petition to Protect Public Health by Repealing the Food Additive Regulations for Seven Pesticides, Before the Environmental Protection Agency, May 25, 1989; and California v. Reilly, filed in federal district court in Sacramento, CA on May 25, 1989.

manufacturers on the effects of those food-use pesticides that have been studied are ominous. Legal levels of residues from just 28 widely-used pesticides could cause cancer in as many as 6 out of every thousand persons.[25] Even if the tolerances were lowered by a factor of ten, or even a hundred, some of these agricultural chemicals would still pose cancer risks which exceed the government's standard for "negligible risk" of one in a million.

IV. THE DELANEY CLAUSE IS VITAL TO THE PROTECTION OF OUR FOOD SUPPLY FROM CARCINOGENIC COLOR ADDITIVES, FOOD ADDITIVES AND ANIMAL DRUGS.

Many food industry representatives, as well as the current Food and Drug Administration, have sought to amend or repeal the three Delaney clauses in the FFDCA.[26] NRDC strongly opposes any such effort. An absolute prohibition on carcinogens is the appropriate standard for regulating food additives, color additives and animal drugs. We would vehemently oppose amendments, even if coupled with improvements to the regulation of pesticides, which undermine the strict Delaney prohibition on those carcinogenic substances used as food additives, color

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[25] NAS, p. 69.

[26] FDA representatives recently told the House Energy and Commerce Committee: "We believe that this [negligible risk"] reasoning reflects good public policy and should also apply to other substances regulated by FDA that are subject to Delaney provisions." Testimony of John M. Taylor, Associate Commissioner for Regulatory Affairs, Food and Drug Administration, before the Health and Environment Subcommittee, House Energy and Commerce Committee, June 23, 1988, p. 4.

additives or animal drugs. Improved safety of the pesticides used in our food supply must not be achieved at the expense of increasing the hazards from other carcinogenic substances in food.

V. S.722 IS ESSENTIAL TO IMPROVE THE SAFETY OF OUR FOOD SUPPLY.

A. S.722 REQUIRES PESTICIDE TOLERANCES TO POSE NO MORE THAN A NEGLIGIBLE RISK, INCLUDING FOR INFANTS AND CHILDREN.

The centerpiece of this bill is the requirement that pesticides used in food must pose no more than a negligible risk, which the bill defines as a rate of adverse human health effects of no more than one in a million. The bill requires that the EPA must ensure that "identifiable population groups (such as infants and other children)" are not subjected to a higher risk level. NRDC regards this provision as essential to public health protection. Average consumption estimates which are derived by dividing the total quantity of a food sold in the U.S. by the total U.S. population has very little relevance to the real consumption by individuals.

EPA's pesticide risk assessments and the resultant regulatory decisions generally assume an "average" diet. However, virtually every individual's diet deviates considerably from that of an average American's. Most people eat high quantities of certain foods and avoid other foods altogether. The consequence is that EPA's pesticide tolerances are designed to protect the theoretically average consumer--not the actual person who eats an apple, or two, a day. Consumers who eat

higher quantities of any food than EPA considers to be average are not necessarily protected by EPA tolerances from developing cancers or other diseases caused by pesticides remaining on food. S.722 would require EPA to ensure that tolerances protect infants, children and other people who eat more than "average" amounts of foods treated with pesticides.

1. Explanation of Children's Enhanced Risk

NRDC demonstrated in our "Intolerable Risk" study that preschoolers have greater exposure to pesticide residues than adults. This is so because preschoolers eat more food, relative to their weight, and consume much larger quantities of fruit, which has a high likelihood of being contaminated with pesticides. Fruit comprises 20% of the adult diet and 34% of the preschooler's diet. Preschoolers eat six times as much total fruit, seven times more grape products and seven times more apples and apple sauce, relative to their weight, than adults. Apple juice is a particular favorite of children. The typical preschool child consumes almost 18 times as much apple juice and the typical toddler more than 31 times as much apple juice, relative to their weight, as the average adult woman.

Fruit is highly likely to contain pesticide residues. The 1987 FDA's food monitoring program found that 50% of all fruit samples had detectable levels of pesticides. This residue rate is higher than that of any other commodity and may significantly underestimate the full extent of residues because FDA's

monitoring program does not routinely monitor for nearly half of the pesticide residues in food.

NRDC's analysis of exposure, based on a USDA study of food consumption by children and women, determined that relative to their weight preschoolers receive much greater exposure than adults to the majority of the pesticides analyzed in this report. The average preschooler receives more than five times greater exposure to the fungicide mancozeb, nine times greater exposure to the neurotoxic organophosphate azinphos-methyl and 12 times greater exposure to UDMH, the carcinogenic metabolite of daminozide, than adults. The typical preschooler receives four times greater exposure, on average, than adults to the eight carcinogenic pesticides evaluated. The youngest children receive the greatest pesticide exposure. Relative to adult women, toddlers receive more than eight times the exposure to mancozeb, 15 times greater exposure to azinphos-methyl and 18 times greater exposure to UDMH, than women.

B. S.722 REQUIRES THAT EPA ACCURATELY ASSESS EXPOSURE.

S.722 strengthens the federal pesticide regulatory program by requiring a more accurate assessment of exposure to pesticide residues as a prerequisite to a new pesticide tolerance. The bill requires that a pesticide legal limit take into account the other uses of the same pesticide on food and the other exposures to the pesticide the consumer experiences through the diet (such as through drinking contaminated water). These provisions are

vital if the pesticide limits are to reflect the actual exposures experienced by our citizens.

The bill requires that exposures be evaluated on the assumptions that all commodities on which the pesticide's use is legal are treated with the pesticide, that the residue levels equal the pesticide tolerance level, and that exposure at the legal limit is likely to occur over a lifetime. These are reasonable assumptions which are necessary to ensure that the exposures of some members of society are not being ignored. The bill provides an exception whenever EPA has reliable data showing that less of the crop is treated and that the treated portion of the crop is distributed in a way which ensures that the risk is distributed evenly among consumers of the commodity. EPA is also allowed to calculate risk based on what they believe to be "actual residue" levels but only if they then lower the tolerance to conform with the actual residue level.

EPA has not routinely lowered tolerances upon a finding that the legally permissible concentrations of pesticide residues would cause high risk of cancer or other adverse effects. EPA often dismisses these findings by stating that residues are normally below tolerance levels, but EPA does not concomitantly lower the tolerances to what it has declared to be the "normal" level. Consequently, people may unwittingly consume foods that, although legal, contain pesticide levels which EPA's data demonstrate to be unsafe.

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Legal food should be safe food. Without prohibitively expensive chemical analyses of all food, consumers cannot identify which foods bear high residues and which have lower, safer concentrations of pesticides. Therefore, EPA should ensure that consumption of food with residues at the legal maximum is safe. EPA should perform risk assessments based on the assumption that pesticide residues will be present at the maximum legal concentration. If EPA, growers or the food industry believe that such a risk assessment overstates the risk, they should demonstrate that actual residues are lower and petition for a lower legal limit. This is how S.722 would function. The bill in effect requires EPA to limit risk to the level which they say results from the actual residues of the pesticide.

C. S.722 REQUIRES THAT EPA ESTABLISHES PRACTICAL METHODS OF ANALYSIS FOR ALL PESTICIDES, EXCEPT WHERE SUCH METHODS ARE NOT SCIENTIFICALLY FEASIBLE.

Pesticides should not be used on food if FDA cannot readily detect the residues in food. Without the ability to detect residues at reasonable cost, FDA cannot enforce EPA's tolerances and therefore cannot protect the public from pesticide residues in food. S.722 recognizes this fact and corrects the current anomalous situation in which dangerous pesticides are used on food which our government agencies cannot routinely find by their monitoring methods.

FDA monitoring for pesticides is inadequate to ensure that residues are legal, let alone safe. Of the 496 pesticides FDA

has identified as likely to leave residues in food, FDA's routine analytical methods can only detect 203--only 41%.[27] Of the 105 pesticides which FDA considers to pose a moderate to high health hazard, only 58 (55%) are detectible using the FDA multi-residue methods.[28] Among the commonly used pesticides which cannot be detected by FDA's multi-residue methods are benomyl, daminozide, the EBDC fungicides and paraquat.[29] Twenty-six of the 53 pesticides identified by EPA as potentially oncogenic for the 1987 NAS report on pesticides in food cannot be detected by FDA's multi-residue method.

EPA should require that manufacturers of pesticides used on food develop practical methods for detecting pesticide residues. An analytical method should be considered practical only if the method: (1) reliably and routinely quantifies the level of residue in food with sensitivity sufficient to enforce the tolerance; (2) provides results in less than eight hours; (3) can be used in FDA labs with existing FDA laboratory equipment; and (4) costs no more than what is typically incurred by the FDA in using a multi-residue method. The bill would encourage the development of multi-residue methods for a wider range of pesticides. S.722 would greatly improve FDA's ability to enforce the pesticide tolerances.

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[27] GAO, Pesticides: Need to Enhance FDA's Ability to Protect the Public From Illegal Residues, October 1986, p. 33.

[28] Ibid, p. 36.

[29] Ibid, p. 39.

D. THE BILL REQUIRES DATA COLLECTION FOR ALL FOOD USES PESTICIDES WHICH HAVE NOT YET BEEN ADEQUATELY STUDIED.

EPA will be collecting important new data on the health and environmental effects of pesticides as a result of the 1988 amendments to FIFRA[30], but it is not clear when or whether EPA will use these data to reestablish tolerances at new levels which will truly protect the public health. S.722 requires the EPA to use this new data to rapidly set new tolerances which will be protective of our entire population.

Pesticides in food are legal up to the tolerance level. Yet residues are not necessarily safe at the tolerance level, or, as NRDC's "Intolerable Risk" report illustrates, even at levels well below the legal limit. This situation has occurred in part because most pesticide tolerances were set in the absence of reliable and complete data on the effects of long-term exposure. In fact, many existing tolerances were established by USDA prior to EPA's existence and were set with great deference to the economic interests of growers. Because the health effects of chronic low-level exposure were generally unknown, tolerance levels often only reflected residue levels resulting from growers' historical uses. Tolerances were routinely set high, so that crops subjected to the most frequent and most concentrated permissible pesticide treatments could legally be sold. EPA inherited these old tolerances from USDA when it was created in

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[30] Federal Insecticide, Fungicide and Rodenticide Act Amendments of 1988, Pub. L. 100-532, October 25, 1988.

1970. Unfortunately, many of these old, high tolerances still remain on the books.

Reregistration and reassessment of old pesticide tolerances are both desperately needed. Currently, petitioners must submit adequate data to support new tolerances. But EPA's process for obtaining data for already-registered pesticides is far less systematic. Although EPA has initiated chronic toxicity data call-ins for most food use pesticides[31], most of these pesticides are missing some crucial data, particularly in the area of residue chemistry. These data gaps have resulted in regulatory paralysis.

To illustrate this persistent problem, the Committee should consider the case of the EBDCs, the most widely-used group of fungicides registered in the United States. Both EPA's decision documents and the recent NAS Delaney report indicate high cancer risks for this class of fungicides.[32] The EBDC fungicides were registered in 1966 and 1967, and a special review of the cancer risks of the compounds began in 1977. In 1982 regulatory action was deferred in part because of incomplete information on exposure to the carcinogenic breakdown product, ETU. NRDC sued the agency, and we reached a settlement with EPA in 1984 when the

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[31] Testimony of Dr. John A. Moore, Assistant Administrator for Pesticides and Toxic Substances, EPA, Regulation of Pesticide Hearing, House Energy and Commerce Committee, June 8, 1987, p. 178. Also see 49 Federal Register 49544, December 20, 1984.

[32] EPA's decision documents indicate a lifetime dietary cancer risk of up to 4.9×10^{-4} (1 cancer in 2,000 persons exposed). NAS estimates for each of four EBDCs was similar. NAS, supra, p. 68.

Agency agreed to demand new data and to reassess the chemical before December 31, 1986. Registrants of these fungicides failed to comply with EPA's deadlines for submitting data. EPA now expects not to receive complete data until mid-1989.[33]

The case of the EBDCs is not unique. GAO reports that only approximately 50% of registrants submit EPA-requested data on old chemicals on time.[34]

Tolerance revision should occur rapidly when EPA learns of new or higher risks than were assumed when the legal limit was initially set as data comes in under in response to the 1984 food use pesticide data call-in[35] or the requirements of the 1988 FIFRA Amendments. S.722 would require appropriately swift action when new data is received.

E. S.722 REQUIRES THAT PESTICIDE INERT INGREDIENTS HAVE TOLERANCES UNLESS THEY ARE CHEMICALS WHICH ARE "GENERALLY RECOGNIZED AS SAFE".

The federal pesticide law distinguishes between active ingredients, which kill, repel or otherwise control pests, and so-called "inert" ingredients, substances which are used to

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[33] Testimony of Dr. John A. Moore, supra, pp. 151-153.

[34] "Data supplied by EPA from the [data call-in] tracking system indicate that about 47 percent of registrant responses to active ingredient data requirements (i.e., chronic toxicity data on the active ingredient) were overdue." General Accounting Office, Pesticides: EPA's Formidable Task to Assess and Regulate Their Risks, GAO/RCED-86-125, April 1986, p. 40.

[35] 49 Federal Register 49544, December 20, 1984.

dilute, propel or stabilize the active ingredient.[36] In many instances, the non-active ingredients are extremely toxic chemicals.[37] EPA has broadly exempted these "inert" ingredients from regulation under the FFDCA. NRDC believes that current law requires EPA to set tolerances for these ingredients. However, we fear that litigation may be necessary to motivate EPA to set tolerances for these dangerous pesticide ingredients.

S.722 requires EPA to revoke the food uses of dangerous "inert" ingredients unless they are "generally recognized as safe" or have a tolerance which ensures that they pose no more than a negligible risk. This provision would greatly enhance food safety. Because many so-called inert ingredients today are actually toxic chemicals, there may be instances in which the pesticide may pose excessive risks not because of the active ingredient but instead because of the substance used to dilute, propel, or stabilize the formulation.

Inert ingredients are generally not essential to the pesticide product. If a manufacturer wants to continue to use the active ingredient in or on food, the manufacturer should substitute an innocuous ingredient for the one posing a significant health threat. If an entirely innocuous ingredient

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[36] The Federal Insecticide, Fungicide and Rodenticide Act, (FIFRA), 7 U.S.C. § 136(a) and § 136(m).

[37] EPA recently listed 57 inert pesticide ingredients of toxicological concern. 52 Federal Register 13305, April 22, 1987. Included on EPA's list were extremely dangerous chemicals, some of them restricted or cancelled by EPA, such as benzene, carbon tetrachloride, chloroform, formaldehyde, and mercury oleate.

cannot be found, the pesticide manufacturer must have the burden of testing the ingredients and demonstrating that at the tolerance level they will pose no more than a negligible risk in combination with the active ingredients. EPA should never allow residues of an inert ingredient to pose a significant health hazard.

F. THE BILL PROVIDES EPA WITH EXPLICIT AUTHORITY TO IMMEDIATELY REVOKE OR MODIFY TOLERANCES WHEN NEEDED TO AVERT AN "IMMINENT HAZARD."

Last year EPA Assistant Administrator Dr. John A. Moore testified before this Committee that under current authorities, EPA's revocation of a tolerance due to a registrant's failure to submit data promptly is labor-intensive and time-consuming. He suggested that revocation, when challenged by registrants, may take years.[38] Dr. Moore expressed the need for a provision in the law automatically revoking tolerances where data-submission deadlines are missed.[39] NRDC believes that food safety legislation should contain provisions automatically revoking tolerances if required data are not submitted in accordance with statutorily-defined deadlines. S.722 provides this necessary authority.

VI. S.722 NEEDS STRENGTHENING IN ORDER TO ENSURE THAT PESTICIDES IN FOOD DO NOT ENDANGER PUBLIC HEALTH. NRDC WILL OPPOSE ENACTMENT OF ANY BILL WHICH WOULD ERODE THE PURELY HEALTH-BASED STANDARD OF S.722 OR WEAKEN STATE POWERS OVER PESTICIDES.

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[38] Testimony of John A. Moore, June 8, 1987, supra, p. 172.

[39] Testimony of John A. Moore, June 8, 1987, supra, p. 178.

A. NRDC URGES THE COMMITTEE TO ADOPT AN AMENDMENT TO REQUIRE THE ELIMINATION OF ALL PESTICIDES WHICH ARE HUMAN CARCINOGENS BY THE YEAR 2000.

Even though S.722 will help to reduce residues of carcinogenic pesticides in food, NRDC believes the bill should ultimately eliminate use of pesticides which are probable human carcinogens. Though the bill is an excellent interim measure, there are reasons to phase out all substances which EPA believes are likely to cause cancer in humans. First, the new tolerances which would be developed under the bill rely on risk assessment, which may understate the risk of certain pesticides. Furthermore, the bill does not ensure that cumulative exposures to carcinogenic pesticides in every American's diet is safe. Finally, the public needs assurance that even if federal agencies' implementation of the new law is no more diligent that their implementation of the old law, there will ultimately be a substantial reduction in the use of carcinogenic pesticides. Particularly given the ubiquitous exposures to other, non-pesticidal carcinogens--from radon and cigarette smoke to automobile emissions--NRDC considers it imperative that Congress take steps to minimize each person's exposure to substances which are carcinogens.

NRDC strongly urges this Committee to require EPA to revoke tolerances for all pesticides which authoritative federal agencies--such as the EPA, the National Cancer Institute, or the National Toxicology Program--identify as "probable human carcinogens." Alternative pest control methods must be sought

for such substances. Pesticide manufacturers and growers will have no incentive to develop innovative crop protection processes as alternatives to carcinogenic pesticides unless there is a congressionally-mandated deadline for eliminating these dangerous pesticides. To allow for the time needed to conduct research in pest management to establish such alternatives, NRDC supports delayed application of such a provision for a number of years. Nevertheless, the American people deserve the assurance that by the year 2000 the foods they consume will not contain any pesticide which has been identified as a probable human carcinogen.

B. NRDC'S SUPPORT FOR S.722 IS CONDITIONED ON CONGRESS' REJECTION OF PROPOSALS TO GIVE EPA AUTHORITY TO CITE ECONOMIC BENEFITS TO JUSTIFY THE USE OF PESTICIDES IN FOOD WHICH POSE GREATER THAN A NEGLIGIBLE RISK.

Tolerances should be set at safe levels. Benefits of the pesticide are irrelevant to the question of how much residue in food is safe. EPA currently interprets FFDCA section 408 as enabling the Agency to balance the risks of pesticide with the benefits of the chemical.[40] NRDC believes such an interpretation is unsupported by the statute, legislative history, or legal precedents. EPA testified before this Subcommittee last year and again earlier this month in favor of authority to grant

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[40] Testimony of John A. Moore, June 8, 1987, supra, p. 170.

tolerances for dangerous pesticides based on considerations of benefits.[41]

Benefits considerations can become an enormous loophole to the strict regulation of widely-used but extremely dangerous pesticides. Those familiar with EPA's implementation of the FIFRA statute have witnessed EPA repeatedly cite economic benefits as the justification for continuing the registration of very hazardous pesticides. Benefits analyses appear to be developed ad hoc for the purpose of retaining current uses. Many of these analyses rely on unsubstantiated claims about the usefulness of the chemical. Seldom does the EPA consider that non-pesticidal crop protection strategies may serve as an alternative to pesticide use. Economic benefits to the pesticide industry or to growers should not be used to justify hazardous residues in our diets.

C. NRDC'S SUPPORT FOR S.722 IS CONTINGENT UPON THE CONGRESS' REJECTION OF ALL EFFORTS TO PREEMPT STATE AUTHORITY TO SET STRICTER PESTICIDE TOLERANCES.

Proponents of amendments which would preempt states' authority to set tolerances say that such amendments are needed to prevent a "crazy quilt" of conflicting legal requirements which complicate or interrupt interstate commerce of agricultural produce. Unfortunately, this assertion lacks an empirical foundation. Experience has revealed that states exercise their

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[41] Testimony of John A. Moore, June 23, 1988, supra, p. 10-11; and Testimony of John A. Moore, Acting Deputy Administrator, Environmental Protection Agency, before the Committee on Energy and Commerce, Subcommittee on Health and the Environment, May 15, 1989.

authority to set more stringent pesticide tolerances cautiously and only in compelling circumstances.

States have acted to set more stringent tolerances only when faced with extreme federal inertia in the face of ample evidence that public health was not adequately protected by federal tolerances. There are approximately three hundred pesticides approved for uses on food. Only two pesticides have been the subject of state efforts to tighten federal tolerances: ethylene dibromide (EDB) and daminozide.

In both instances where states set tolerances more stringent than the federal limits, many years of federal inaction or ineffective efforts preceded state action. In both instances compelling evidence was available on the basis of which state health authorities concluded that the risks from these pesticides were great, particularly for children. Both times the states tried to motivate the federal government to act and probably would have preferred swift and decisive federal action. The EDB and daminozide incidents did not stem from a surplus of conflicting and overlapping authorities to set tolerances. Instead, these events demonstrate the confusion and danger which result from the federal government's failure to exercise its authority to revise tolerances when new data reveal high risks.

1. Ethylene Dibromide (EDB)

Ethylene dibromide was first registered for food uses in 1948. EDB was used as a soil fumigant to kill nematodes as well as a post-harvest fumigant for grains and citrus. In 1956, on

the basis of assumptions that no residues would remain on foods, EDB received an exemption from tolerance. The National Cancer Institute identified EDB as carcinogenic in 1974. In the late seventies, evidence established that contrary to expectations residues of EDB persist in food. EPA also obtained information confirming EDB's acute toxicity and adverse reproductive effects. Nevertheless, EPA's 1980 preliminary decision to cancel use of EDB was halted after Reagan Administration officials met with representatives of the food industry.[42]

In 1983 EPA took the first of a series of steps to limit use of EDB. EDB's use as a soil fumigant was suspended in September of 1983.[43] At the same time, EPA also began cancellation of the use of EDB as a grain and citrus fumigant, to become effective on September of the following year.[44] In February of 1984, uses of EDB on stored grain and grain milling equipment was suspended on an emergency basis.[45] Finally, in March of 1984, EPA announced a "phase out" over the next six months of EDB used to fumigate citrus.[46]

Despite these efforts to stop the domestic use of EDB, EPA still took no action to limit residues in food. Instead, Agency

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[42] See Problems Plague the Environmental Protection Agency's Pesticide Registration Activities, House Committee on Government Operations, U.S. House of Representatives, 98th Congress, 1984.

[43] See 48 Federal Register 46228, September 28, 1983.

[44] See 48 Federal Register 46234, September 28, 1983.

[45] See 49 Federal Register 4452, February 3, 1984.

[46] See 49 Federal Register 17144, March 2, 1984.

officials, including former Administrator Anne Gorsuch, convened numerous meetings with other Administration officials and representatives of food processing companies which are now spearheading this preemption effort in the Congress.[47] Although these food companies were able to persuade some Administration officials to delay action on EDB, they had less noteworthy success in certain states. NRDC believes that the drive to preempt the states was fueled by the frustration and surprise that certain food companies experienced when their influence in Washington, D.C. did not translate into power in the state capitals.

EPA calculated the dietary risk from EDB residues in grains as 3.3 cancer cases per 1,000 individuals exposed.[48] This calculation did not include risk from dietary exposure to EDB residues in citrus or to EDB in drinking water. Actual residue testing done by some private and state laboratories indicated significant residues in many common foods. States began to exert their authority to protect citizens from exposure to EDB. Eight states required that baby food products have no detectable residues of EDB.[49] Some states also established tolerances for EDB in other foods. Finally, in April 1984, EPA established

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[47] See Problems Plague the Environmental Protection Agency's Pesticide Registration Activities, House Committee on Government Operations, U.S. House of Representatives, 98th Congress, 1984.

[48] Environmental Protection Agency, Ethylene Dibromide: Position Document 4, September 1983, page 69.

[49] California, Connecticut, Florida, Maine, Massachusetts, Michigan, New York and Texas.

tolerances for EDB in foods--but the federal limits were higher than those already set by some states.

2. Daminozide and UDMH (Unsymmetrical Dimethylhydrazine)

The Agency's experience with daminozide (Alar) is not dissimilar to the EDB story. Daminozide, a growth regulator, was first registered for use on apples in 1969. Daminozide is primarily used on apples, but it is also used on peanuts, cherries, grapes and other fruits. Apples treated with daminozide ripen more slowly and are less likely to drop before harvest, are denser and store better, and have an enhanced color. However, five separate pre-1985 studies demonstrated the carcinogenicity of daminozide and its metabolite, unsymmetrical dimethylhydrazine (UDMH). Toxicological evidence suggested that UDMH may be an even more potent carcinogen that daminozide itself. New data also revealed that the transformation of daminozide into UDMH is accelerated by heating, as occurs during cooking or processing apples into applesauce and apple juice.

Because of the accumulating evidence of the carcinogenic potential of daminozide and UDMH, by 1985 many states were concerned about the danger posed to infants and children who consume processed apple products such as apple juice and applesauce at disproportionately high levels compared to adults. Several states also recognized that children may be even more vulnerable than adults to carcinogenic exposure because of their incompletely developed immune systems and the greater likelihood that they will live beyond the latency period necessary for the

development of cancers. Children's more rapid rate of cell development may also make them more susceptible to carcinogens.

Although the first study demonstrating a cancer risk was performed in 1973, there was no hint of regulatory action on daminozide until seven years later. Then in 1980 EPA initiated a series of closed-door meetings with the sole manufacturer of daminozide, Uniroyal.[50] In September 1985, EPA proposed to stop any further food uses of daminozide. Uniroyal insisted that the carcinogenicity studies were flawed, although the flaws noted were ones which would normally understate the risk. However, Uniroyal never initiated its own carcinogenicity tests on their product. EPA's Scientific Advisory Panel on September 27, 1985 overturned EPA's staff recommendation to cancel daminozide. EPA granted Uniroyal four more years in which to conduct new cancer studies.

The chief public health officials in the states of New York and Massachusetts wrote to EPA in 1985 to register their concern about the risk from daminozide, particularly for children. These health officials recommended restriction or cancellation of food uses of daminozide.[51] However, in January 1986, EPA reversed its

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[50] In accordance with a settlement obtained with EPA by NRDC and the AFL-CIO, this practice of secret consultations with pesticide manufacturers has been discontinued. Settlement agreement in NRDC et al. v. Ruckelshaus, No. 83-1509, (D.D.C., September 20, 1984.)

[51] Letter of Dr. Bailus Walker, Commissioner, Department of Public Health, The Commonwealth of Massachusetts, to Mr. Steven Schatzow, Director, Office of Pesticide Programs, U.S. Environmental Protection Agency, January 16, 1985; Letter of (continued...)

position and continued existing uses of daminozide, pending further study.

EPA also proposed on April 16, 1986 to reduce the tolerance for daminozide-treated apples from 30ppm to 20ppm.[52] Massachusetts has taken measures to minimize exposure to daminozide.[53] Inordinate delays at the federal levels led other states, including Maine and New York, to consider regulatory action to protect public health from daminozide.[54]

On February 1, 1989, based on data from the halfway point in a new Uniroyal UDMH study, EPA announced concern about the occurrence of statistically significant increases in unusual blood vessel tumors in mice. From this study EPA estimated an alternative cancer potency factor which is lower than that

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[51](...continued)
David Axelrod, M.D., Commissioner of Health, State of New York to Dr. John Moore, Assistant Administrator, Office of Pesticide Programs, U.S. Environmental Protection Agency, October 25, 1985.

[52] See 51 Federal Register 12889, April 16, 1986. The rule implementing the tolerance modification became effective on January 16, 1987. See 52 Federal Register 1909, January 16, 1987.

[53] Action Levels for Poisonous or Deleterious Substances in Food, Mass. Admin. Code Tit. 105, 515.000 (1986).

[54] State of Maine Department of Agriculture, Notice of Agency Rulemaking Proposal, Daminozide/UDMH: Acceptable Residue Levels in Heat Processed Foods, May 28, 1986. Testimony of Ms. Marilyn DuBois, Chief, Bureau of Pesticide Management, New York Department of Environmental Conservation, before the Department Operations, Research and Foreign Agriculture Subcommittee of Agriculture Committee, U.S. House of Representatives, June 10, 1987.

derived from the pre-1985 studies.[55] The new Uniroyal study further corroborates carcinogenicity findings from pre-1985 laboratory tests, demonstrating once again that the earlier studies provided a reasonable basis for estimating the cancer risk from UDMH.

3. States have Rarely and Cautiously Exercised their Authority to set more Stringent Tolerances.

States have never used their authority to set distinct tolerances where the federal government has already set adequately protective limits for permissible pesticide residues on foods. State authority has been used judiciously and only after protracted delays at the federal level. No state has used its tolerance-setting authority to interfere with interstate commerce or to block the importation of produce from other states. Instead, divergent tolerances have been based on weighty evidence that the dangers of EDB and daminozide were being inadequately addressed by EPA. State power to set tolerances must be preserved to enable states to protect their citizenry when the federal government cannot or will not respond to pesticide problems.

VII. CONCLUSION

NRDC applauds the Chairman for this important piece of legislation to ensure that pesticides in food are safe. Legislation of this kind is urgently needed to restore public

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[55] NRDC requested, but was not given, EPA's revised UDMH cancer potency factor before we released our report.

confidence in our federal programs to protect our food supply. We urge the Committee to challenge those who maintain that this bill would result in enormous losses to agriculture. NRDC believes that there is no evidence to justify such claims. This bill does not require the banning of pesticides whenever they pose a risk. Instead, the bill wisely requires that residues of dangerous pesticides must be limited to a level which is safe for all members of society. This bill would require EPA to phase out the uses of pesticides only when the chemicals are so dangerous that they cannot be used in agriculture effectively at levels which pose a negligible risk to the public. The American public is demanding a vastly safer food supply. We hope to work with this Committee ensure that the public's demand is heeded.

The CHAIRMAN. Ms. Bloom.

Ms. BLOOM. Thank you. My name is Anne Bloom, and I am a staff attorney with Public Citizens Congress Watch. With me is William Schultz, who is an attorney with Public Citizens Litigation Group. Public Citizen is a national nonprofit consumer and environmental advocacy organization. We appreciate this opportunity to testify today on the important issue of food safety.

Unfortunately, we do not have a written statement, but we would like to submit one at a later time.

Thank you.

We think it is significant that the administration has come forth with the proposal because it demonstrates that there is a problem in food safety. At least now we can all agree about the fact that there is a problem that needs to be fixed and debate can begin on the details of the solution.

EPA has done a terrible job, and as a result, the public has lost confidence in the Federal Government's ability to ensure the safety of the food supply. Most recently the Alar story focused attention on the excessively slow regulatory process and the health-threatening nature of some of the pesticides that are used on food today. In this regard we have to acknowledge that of the 400 pesticides that are approved for use on food, EPA has completed review of only a handful. And a few years ago the National Academy of Sciences released a report that documented that there are very real risks associated with pesticides in food and that the standards we are using now are inconsistent. This report also warned of the coming controversies as EPA reviews new health and safety data on many of the older pesticides.

Although the administration's proposal contains many measures that suggest theoretical advances in food safety, it fails to provide the framework needed for real progress. For example, the proposed changes in suspension and cancellation are clearly designed to speed up the process, and the enhanced enforcement provisions may give EPA more authority, but what we don't see are real provisions that would guarantee a real improvement in public health.

The bottom line with the public health problem associated with pesticides is that people are being unnecessarily exposed to health-threatening pesticides in their food. The best way that we can solve this problem is to take positive steps toward reducing exposure to the pesticides that pose the greatest risks.

To reduce exposure, there are at least three critical issues that must be addressed and that the President's proposal does not contain. One, there is a need for tight timetables for the policy reforms that are being implemented. The President's proposal gives the agency the authority to speed up the process, but it could still take a very long time. We need strict timetables.

Two, there is a real need to tighten the standards that apply to pesticides. EPA's current risk assessment scheme leaves too much room for manipulation of the data and inaccuracy. Unfortunately, the President's proposed standard is also inadequate. It relies on risk assessment and allows risks that are too high.

We support the Kennedy-Waxman bill, S. 722, which we believe strikes a much better balance. Even better would be an amend-

ment to S. 722 that would phase out the use of carcinogenic pesticides in food.

The third thing that is needed to reduce risks associated with exposure to pesticide residues in food is that we need to require that EPA eliminates consideration of benefits when it determines which pesticides are safe for use on food. As history has shown us, once you start counting in the benefits, there are no controls on EPA and the agency ends up approving very-high-risk pesticides. Permitting the consideration of benefits takes away the ability to set, the ability of the law to set tolerance levels that are truly protective of human health.

Before closing, we would like to add that, in light of EPA's history on pesticide regulation, it seems especially inappropriate to permit the Federal Government to preempt States' authority to set more protective tolerances levels. We very strongly oppose the preemption provision in the administration's proposal.

Thank you. We would be happy to answer any questions.

[The prepared statement of Ms. Bloom follows:]

PREPARED STATEMENT OF ANNE W. BLOOM

Public Citizen appreciates the opportunity to submit this written statement on the President's Food Safety Proposal and S.722, "The Food Safety Amendments of 1989."

Public Citizen is a national, nonprofit, consumer and environmental advocacy organization founded by Ralph Nader in 1971. We have a longstanding interest in promoting laws that are designed to minimize the risks of adverse health and environmental effects associated with pesticide use. This work has included litigation seeking a ban on Alar, and more recently, a lawsuit and petition challenging the Environmental Protection Agency's (EPA, failure to identify cancer-causing pesticides in processed food and to apply the Delaney anti-cancer clause. Public Citizen was also active in supporting last year's successful efforts to amend the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

Public Citizen believes that pesticides are the most dangerous category of preventable substances currently found in food. Surveys indicate that the public agrees. A recent study by E.I. du Pont de Nemours and Company found that consumer concern about pesticides is "high and getting higher." The research also found that consumers prefer a "zero tolerance" for chemicals posing health risks.[1]

The President's announcement of an Administration food

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[1] Reported in 17 Pesticide & Toxic Chemical News, No. 51 , at p.5 (October 25 , 1989).

safety proposal confirms the seriousness of America's food safety concerns. Unfortunately, the Administration's proposal does not provide the framework that is needed for real progress in tackling the food safety dilemma.

The root of the food safety problem lies with the EPA. As the Alar controversy demonstrates, the EPA's regulation of pesticides is a disaster. The Alar story focused attention on the excessively slow regulatory process and the health-threatening nature of some of the pesticides used on food. Alar is not alone. Of the over 400 pesticides approved for use on food, the EPA has completed the health and safety review of only a handful.

A few years ago, the National Academy of Sciences (NAS) released a report that documented that there are real health and environmental risks from exposure to food-borne pesticides and that the standards the EPA uses to regulate pesticide residues in food are inconsistent. The Academy's report also warned of the coming controversies as the EPA reviews the new health and safety data on many older pesticides. To date, the agency has identified at least 66 pesticides that potentially cause tumors. Outcries like that with Alar can be expected again and again until pesticide regulation is reformed.

Public Citizen is convinced that the EPA's failure to adequately regulate potentially health-threatening pesticides is not the fault of food safety laws but rather a lack of Agency

will. For example, the current Federal Food Drug and Cosmetic Act (FDC Act) does not mandate a "negligible risk" standard or require the balancing of the "benefits" of food use pesticides against their risks. Yet these are the guidelines that the PEA has used in setting tolerances for pesticide residues in food. Moreover, the Agency's attempt to avoid the Delaney anti-cancer clause with a "de minimis" interpretation is, in our view, illegal. A de minimis interpretation to the Delaney Clause in the Color Additive Amendments to the FDC Act was held impermissible by the United States Court of Appeals for the District of Columbia, in a case brought by Public Citizen. Public Citizen v. Young 831 F.2D 1108 (D.C. Cir. 1987). We are currently engaged in litigation over the EPA's attempt to implement a de minimis policy.

Because the EPA has failed to implement the law, legislation is required to assure the safety of the food supply. Public Citizen supports the legislative solution put forth in Chairman Kennedy's bill, S. 722, The Food Safety Amendments of 1989. In contrast to S. 722, President Bush's proposal would mark a significant retreat from the protection already provided in current law against dangerous pesticides in our food. The consumer and environmental community is united in opposition to the Administration's proposal.

Although the President's proposal contains many measures that suggest theoretical advances in food safety -- it does not provide for genuine reform in the ways we regulate pesticide

residues in food. While we recognize that the proposed changes in suspension and cancellation are clearly designed to speed up the process, and that the enhanced enforcement provisions may give the EPA more authority, what we do not see are provisions that would guarantee a real improvement in public health.

The bottom line public health problem is that people are being unnecessarily exposed to health threatening pesticides in their food. The best way that we can solve this problem is to take positive steps toward reducing exposure to those pesticides that pose risks. To successfully reduce exposure to the riskiest pesticides there are at least three critical issues that must be addressed and all three are missing from the President's proposal.

First, there is a need for tight timetables for the policy reforms that are being implemented. This has been a problem in the past with implementation of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and it will be a problem again if new legislation fails to include a time-line for implementation of the reforms. Without timetables, it makes little difference that the President's proposal gives the EPA the authority to speed up the process; removal of problem pesticides could still take a dangerously long time.

Second, there is a need to tighten the standards that apply to pesticides. The EPA's current risk assessment scheme leaves too much room for inaccuracy and manipulation of data. Implementation of the Administration's principles would do little

to correct this problem, and it would allow risks that are far too high. The White House proposal would routinely permit the use of pesticides that pose risks of cancer as great as one additional cancer per 100,000 people who consume the contaminated food. Pesticides posing even greater risks could be approved if the agency finds that the so-called "benefits" of pesticide use outweigh the risks. This aspect of the President's proposal is a significant step back from the current Delaney anti-cancer clause which prohibits the presence of cancer-causing pesticides in some foods. Such a change unnecessarily jeopardizes public health.

The Kennedy-Waxman bill, S. 722, strikes a much better balance in assessing risks and benefits. While we take issue with some of the provisions in S. 722, we support the bill because it significantly strengthens current law in a way that would force EPA to do a better job in regulating pesticides.

While S. 722 would permit risks as high as one additional cancer per million persons exposed, a number of improvements would ensure that one in one million would be the highest permissible risk from exposure to food-borne pesticides. For example, S. 772 would require EPA to consider the cumulative risk posed by a variety of pesticides approved for use on the same food. Chairman Kennedy's bill would also require the agency to consider the health and environmental risks associated with "inert" or non-active ingredients in pesticides. The Administration proposal ignores both of these issues, an omission which could result in the EPA underestimating greatly the actual

risk from exposure to a food use pesticide.

The most significant weakness in Chairman Kennedy's bill is that it fails to include a mandatory phase-out of all pesticides found to induce cancer in animals. In this regard, the bill is weaker than current law, which bans cancer-causing pesticides in processed foods that concentrate above the tolerance in the raw product.

The Alar Crisis teaches that the American people would choose against carcinogens in their food supply if given the choice. Truly protective legislation should do nothing less. Public Citizen supports a phase-out of all cancer-causing pesticides.

The third key to pesticide risk reduction -- yet missing from the President's food safety proposal -- is a requirement that the EPA eliminate the consideration of so-called "benefits" in determining which pesticides are safe for use on food. As history has shown -- there are not controls once the EPA starts weighing benefits, and the agency ends up approving very risky pesticides.

The principal problem with permitting the consideration of benefits is that there is no acceptable method of balancing a pesticide's monetary benefits to industry against its risks to consumers. Although the benefits provision has been in current law for 35 years, the EPA has yet to design any systematic means of measuring benefits or any method of weighing those benefits against human health risks.

President Bush's proposal permits the EPA to continue to use the economic "benefits" of pesticide use to justify leaving dangerous pesticides on the market. In effect, this would make the agency's decisions as to whether to allow pesticides on the market almost completely discretionary, insulating those decisions from any effective review by either Congress or the courts. Although pesticide manufacturers claim that pesticides provide "health benefits" to the public, we see no evidence that food-borne pesticides have any health benefits that would justify exposing the public to significant risks.

One of the most important strengths of Chairman Kennedy's bill is that it would eliminate the EPA's consideration of benefits in evaluating pesticides that leave residues in and on food. The FDC Act takes this approach with respect to food additives, color additives, and a number of other substances. Thus, in determining whether to allow the use of a food additive, the FDA evaluates only the risk of the substance, and will ban the food additive if it finds that it is not safe. The same approach should be adopted for pesticides.

The President's proposal seeks to preempt state regulation of pesticide residues in food. Public Citizen strongly opposes this provision. The real world effect of preemption is to cut back on the states' authority to protect its citizens. In a climate where the EPA is not regulating, it is critical that the states be allowed to enact more stringent pesticide legislation.

It is clear that citizens care deeply about the presence of potentially cancer-causing pesticides in their food and that the EPA has failed to give the public the assurance of safety to which it is entitled. What is needed is a federal regulatory policy that ensures to the maximum extent possible that cancer-causing pesticides do not appear in the food supply.

Public Citizen supports S. 722, the Food Safety Amendments of 1989, as a clear improvement over current law. S. 722 effectively responds to the public's concern about the safety of pesticides and would significantly improve current regulation of pesticides residues in food. A more detailed statement of Public Citizen's support for S. 722 was submitted to the Committee in June of this year.

The CHAIRMAN. Thank you.

Mr. Groth?

Mr. GROTH. Thank you, Mr. Chairman. My name is Ed Groth. I am a scientist with Consumers Union in Mt. Vernon, New York. We are the publisher of Consumer Reports magazine and a leading consumer advocacy organization. I am here to talk about the administration's food safety proposals in the context of the initiatives already proceeding in Congress, specifically S. 722.

As a response to S. 722, the President's food safety plan is disappointing, to say the least. Bold leadership is needed, but the President has offered a ringing defense of the status quo. The public has cried out for reduced risks from pesticides in foods, but the President proposes instead to define existing risks as negligible, and moreover he offers EPA some new ways to justify tolerating greater than negligible risk.

Consumers are demanding reform of pesticide laws and practices, but the President has endorsed an industry hobby horse that was a stumbling block to reform for many years, and that is the preemption aspect.

I will comment briefly on two aspects: negligible risks and the risk-benefit approach. CU—Consumers Union, that is—supports in concept the negligible risk approach and applying it uniformly to all tolerances. But we much prefer the definition of negligible risk in S. 722 to the definition in the President's proposals. Negligible is a value judgment, plain and simple, it is not a scientific measure. The issue before Congress today is what level of risk the American public should be willing to accept from pesticides in our food supply. Clearly, 1 in a million is a much more protective standard than 1 in 100,000 or, as Janet has pointed out, greater than 1 in 100,000 if EPA finds reasons to justify accepting a larger risk.

Another aspect that the President's plan has failed to address is the additive nature of risks. There are something like 70 different carcinogenic or suspected carcinogenic pesticides in use today. And if we assume just for a ballpark estimate that with 70 pesticides used on many different foods there might be 1000 tolerances for carcinogenic pesticides, that each tolerance could permit a risk of 1 in 100,000 or higher in special circumstances, then the math shows that the risks in theory could be as large as 1 in 100.

S. 722 does address the problem of additive risks. The President's proposals do not. S. 722 does address the problem of risks to sensitive groups, like children and pregnant women. The President's proposals do not.

Perhaps the most disappointing aspect of the President's approach is that essentially it defines what EPA does now. The criteria for negligible risk or acceptable risks are really what EPA has been applying under its tolerance-setting provisions for pesticides.

So at a time when the public is crying out for reduced risks, the President is defining current practice as good enough. We say Congress must do better than that.

Another aspect in which the President's proposals are flawed is that they expand the agency's discretion to apply risk-benefit criteria to setting safety standards for pesticide residue.

On the surface it seems sensible to consider alternatives and weigh the trade-offs and the risks of various approaches. In theory,

EPA might conclude that we really don't need most of the pesticide uses that provide only cosmetic benefits for foods, that those benefits are worth sacrificing to improve the safety of the food supply. But the door swings both ways. EPA could also decide that those benefits are so important that the public should accept the risks.

What EPA calls flexibility we think is additional administrative discretion for the agency, and we would ask Congress one question before you grant that discretion to the agency: Do you think that the amendments will give EPA the political courage to exercise its discretion wisely? Based on the record so far, we don't think so, and we urge you not to give the agency more discretion but to give it less in this area.

I won't address the uniform national standards aspect. My colleagues have covered it well.

We do believe that the enhanced criteria for suspension of pesticides when they are under suspicion of being hazardous is an improvement. However, we think the agency already has that authority. So it is largely a cosmetic improvement. The streamlined cancellation process is another slight gain. Periodic reregistration and increased enforcement authority are all sensible changes.

Just a few words about some fundamental concerns. First, the President's proposal is not really about risk reduction, it is about risk justification. The public has made one thing absolutely clear, and that consumers don't want carcinogenic residues in their food supply. They want to see a national plan for phasing out such pesticides and eliminating unacceptable risks. They don't want to be told by their President to accept those risks because they are negligible.

More to the point, in order to remove these risks, we really need to think of a long-term strategy for reducing the use of pesticides in agriculture, for a transition to the kind of future that the recent NAS report on alternative agriculture envisioned.

The President's plan has no vision to it. It is purely reactive. It is a response to the Alar debate. It is a response to the initiatives now in Congress. But it has no analysis of what we really need to get from where we are today to where we would like to be.

Throughout these tumultuous debates of the past year, Consumers Union has hoped that 1989 would be a turning point, a time when our society finally committed itself to produce our food with minimal damage to our health and the environment. The President's response is essentially to offer "more business as usual." Congress must go beyond the President's limited vision and begin to chart a path to that better future we all know we can and must achieve.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Groth follows:]

PREPARED STATEMENT OF EDWARD GROTH III

Mr. Chairman, Members of the Committee: My name is Ned Groth, and I am Associate Technical Director of Consumers Union,* in Mount Vernon, NY. I am here today to discuss our assessment of the President's Food Safety Plan, announced last week, and to compare the Administration's proposals with those of S. 722, the Food Safety Amendments of 1989.

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* Consumers Union is a nonprofit membership organization, chartered in 1936 under the laws of the State of New York to provide information, education and counsel about consumer goods and services and the management of family income. Consumers Union's income is derived solely from the sale of Consumer Reports, its other publications and films. Expenses of occasional public service efforts may be met, in part, by nonrestrictive, noncommercial grants and fees. In addition to reports on Consumers Union's own product testing, Consumer Reports, with approximately 4 million circulation, regularly carries articles on health, product safety, marketplace economics and regulatory actions which affect consumer welfare. Many of these articles relate to the safety of foods and other household products. Consumers Union's publications carry no advertising and receive no commercial support.

Consumers Union (CU) is already on record in support of the major provisions of the Food Safety Amendments of 1989. We have presented testimony on the House version of the Bill (H.R. 1725) on May 31 of this year; a copy of our testimony is attached for the record.

As a response to S. 722 (and H.R. 1725), the President's Food Safety Plan is disappointing. Bold leadership is needed, but the President has offered a ringing defense of the status quo. The public has cried out for reduced risks from pesticides in foods, but the President proposes to define existing risks as "negligible," and offers EPA some new ways to justify tolerating larger-than-negligible risks. Consumers are demanding reform of pesticide laws and practices, but the President has endorsed the Federal pre-emption of state standards, a goal of food industry interests that was a stumbling block to earlier FIFRA reform. Although many of the President's proposals seem moderate and sensible on first reading, upon deeper reflection, CU finds it difficult to be very enthusiastic about any of them.

We will comment briefly on each of the initiatives in the White House proposals, dealing first with those we judge most important: The definition of "negligible risk;" the use of risk/benefit trade-offs to set health standards; and pre-emption of state rights to set separate, stricter standards on pesticide residues.

(1) Negligible Risk

CU supports in concept a uniform "negligible risk" standard applied to pesticide residues in all foods, as proposed by the National Research Council in its 1987 report about "The Delaney Paradox." However, we much prefer the approach and definition of "negligible" in S. 722 to those contained in the President's Food Safety Plan.

"Negligible" is a value judgment, not a scientific measure. The issue before Congress today is what level of risk the public should be willing to accept from pesticides in the food supply. S. 722 has defined a risk of up to one cancer case per million exposed consumers as "negligible." CU endorses that standard; we oppose the President's proposal to accept, routinely, risks up to 10 times larger, or one cancer case per 100,000 consumers. Moreover, we believe the President is proposing to give the EPA too much discretion to accept risks even larger than that, by expanding the assessment of trade-offs associated with a given pesticide use.

S. 722 contains additional important provisions that are missing from the President's proposals. S. 722 requires EPA to consider the additive nature of risks from different pesticides present on multiple foods, but the President's plan ignores this need. To illustrate this point, let's assume that there are 50 widely-used carcinogenic pesticides, each used on an average of 20 foods, requiring 1000 separate tolerances (a reasonable ball-

peak figure). Under the President's proposals, each tolerance could permit a risk as high as one per 100,000, and some could permit higher risks. The theoretical maximum aggregate risk from 1000 tolerances could therefore exceed one cancer per 100 consumers. Because it looks at each tolerance as an isolated case, the Administration's approach is severely flawed. Real consumers eating actual diets are exposed to multiple residues, and risks can add up to much greater than "negligible."

Another deficiency in the President's proposed approach is the lack of attention it pays to the need to set tolerances for specific age groups and other subpopulations. Tolerances must protect the most vulnerable consumers, such as pregnant women and young children. The NRDC study "Intolerable Risk," despite the controversy it generated, provided an important scientific insight: More than half the total lifetime risk from some pesticide residues can occur before the age of six, because young children are proportionally greater consumers of fruits, juices and vegetables. A risk that looks "negligible" based on the food intake of a typical adult may in fact be much greater than "negligible" when dietary patterns over the entire lifetime are considered. S. 722 has addressed this issue; the President's plan is silent on it.

Perhaps the most disappointing aspect of the President's approach to defining "negligible risk" is that it essentially describes what the EPA does now. EPA already allows risks as

large as one per 100,000 from pesticide residues, and if faced with exceptional benefits, has occasionally tolerated risks even greater than that. At a time when there is strong public sentiment that current practices allow too much risk from pesticides in the diet, and consumers are demanding a reduction in those risks, the President has proposed to define the risks allowed by present practice as "safe enough." We say: Congress must do better than that.

(2) Risk-Benefit Approaches in Tolerance-Setting

The inherent conflict between the two major sections of the FFDCA that provide for pesticide tolerance-setting is that tolerances for raw produce are risk/benefit judgments, while those for processed foods are not. Harmonizing the approach in these procedures is a sensible goal. But the President's proposals would go much farther than that; they would broaden the criteria for risk/benefit assessments in tolerance setting. CU believes that is absolutely the wrong direction to go.

On the surface, the President's proposals seem sensible. It is reasonable for the EPA Administrator to consider and compare the risks of alternatives when setting standards. In theory, if EPA is required to weigh the risks of not using the pesticide at all against the risks associated with using it, the agency could determine that the primarily cosmetic benefits that are the sole reason for a great many pesticide uses are worth sacrificing in

exchange for reduced risks. But EPA might also judge the risks of not using a pesticide unacceptable, and thus find additional reasons to expose the public to non-negligible risks.

The President's proposals, under the guise of "flexibility," give the EPA more explicit mandates to exercise administrative discretion than it has now. We think such "flexibility" would undercut the "predictability" the Administration also seeks. In point of fact, CU thinks EPA already has the authority to weigh all the trade-offs spelled out in the President's proposals, in its general mandate to decide whether a risk is "unreasonable." When Congress ponders whether to give the Agency explicit, new discretion, we ask you whether these proposals will give EPA the political courage to use its new discretion wisely. We do not think it will. We urge that EPA be given less, not more, discretion to make trade-offs that increase risks to consumers.

Instead of the President's case-by-case, let's-look-at-the-trade-offs approach, CU believes the approach in S. 722 is far sounder. S. 722 says, in effect, that we accept as given that pesticides have benefits, and that the risk society is willing to accept in return for those benefits should be no more than negligible. That would be a clear, predictable standard. CU thinks Congress can increase public confidence in the regulatory process more effectively by spelling out precisely what that acceptable level of risk should be than by supporting proposals that would make "acceptable" whatever level of risk the EPA

decided was justified in a given case.

(3) Uniform National Standards

The logic of the need for this provision frankly escapes us. On one hand, the ideal situation would be for the EPA to adopt strict, health-protecting standards based on the latest and best scientific data, for all pesticide tolerances. Yet, if the EPA should fail to accomplish that in a timely way, the public must not be left inadequately protected. The states' right to enact their own, stricter standards is a "safety net" that history has shown us has occasionally been needed.

CU has not seen much evidence of the "adverse effects" that the White House says result from permitting states to set their own standards. The often-cited "crazy quilt" is an imaginary horror. In practical terms, the strictest standard adopted by a major state would become a de facto national standard; companies are unlikely to produce foods to different specifications for different states. The often-voiced fear that state standards might be less grounded in good science than EPA actions seems specious; certainly some states, such as California, appear as capable as EPA is of basing their standards on the best current evidence. CU has not seen states rushing to establish their own standards; the vast majority defer to EPA, even when controversy exists over the adequacy of EPA's actions. And CU has seen no evidence of "consumer confusion" over dual standards, a problem

the White House says its proposal would solve.

Some elements of the President's proposals are inconsistent with the idea of Federal pre-emption. The President's proposals anticipate that the science of risk assessment will continue to advance, and require EPA to review and re-register pesticides in a nine-year cycle. New evidence and new problems may arise that EPA cannot deal with promptly, given the volume of its routine business. If the EPA proves unable to review major pesticides as rapidly as the progress of research indicates it should, it would not be unreasonable to allow the states to act.

In short, we see no good reason to pre-empt the states from independent action, even after the EPA's reregistration process has gone full circle. If the EPA is doing its job effectively, there will be no reason for states to act on their own, and it does no harm for them to have that power in reserve. If the EPA is not doing its job, the states must have the back-up power to act, and to take away that power would weaken public-health protection. Either way, pre-emption seems to offer nothing that justifies the likely political cost of the President's effort to include this business hobby-horse in current reform legislation.

(4) Other Aspects of the President's Plan

We will briefly highlight our responses to other elements of the Administration's proposals, which we consider less important than the three topics already addressed.

o Enhanced Criteria for Suspension

CU supports the goal of permitting the EPA to remove a pesticide from the market while serious questions regarding risks it may pose are resolved. Such action by EPA seems essential to the credibility of the regulatory process, and we support the President's commitment to the principle that public health must take priority over benefits to agriculture in such situations. However, we believe EPA already has the authority it needs to suspend pesticides strongly suspected of posing major hazards. The changes the President has proposed seem largely cosmetic.

o Streamlined Cancellation Process

The improvement is welcome, but this change is comparatively minor if in fact compounds subject to cancellation proceedings will be off the market while those proceedings are carried out.

o Periodic Reregistration

A sensible improvement. This proposal raises the issue of whether the Administration's budget proposals will provide the resources EPA will need to maintain such an enormous, ongoing review process. It is not clear yet whether EPA will be able to accomplish the nine-year review of "old" ingredients mandated by FIFRA 1988, let alone to sustain such a level of evaluations for an indefinite period.

o Increased Enforcement Authority

Also sensible improvements. Having the power to require record-keeping on pesticide use might have spared the EPA the embarrassment of greatly understating the extent of Alar use on the 1988 apple crop, an error that exacerbated public concerns about the inadequacy of the agency's control effort.

(5) Some More Fundamental Concerns

Perhaps our greatest disappointment with the President's Food Safety Plan is not over the proposals themselves, but over what the proposals fail to address. The President's plan seems reactive in nature: It's a response to the Alar crisis of 1988, and a response to the initiatives now in Congress. It lacks any vision, any perceptive analysis of the underlying problems, or of how our society can get from where we are today to where we'd like to be. Here are several issues the President's plan should have addressed, but didn't:

Risk Reduction

The President's plan makes no commitment to aggressively seek to reduce the aggregate risks posed by pesticides in the diet. It doesn't define an overall level of risk that society should accept from our food production practices; instead, it endorses criteria that, applied over recent years, have largely tolerated current risk levels.

If one thing is clear from the Alar debate, it is that consumers do not want carcinogenic residues in their foods. They want to see a national plan to eliminate such unacceptable risks, not to be told by the President that they should accept the risks because they are "negligible."

Alternative Pest-Management Techniques

From discussions with growers, we believe most farmers are as eager to avoid using carcinogenic pesticides as consumers are to avoid eating the residues. But farmers need alternatives, and they need incentives to use alternatives that may pose some additional risks of reducing crop yield or jeopardizing their livelihood. The President's proposals would require EPA to consider the availability and relative risks of alternative forms of pest control (and alternative chemicals) when deciding the fate of a pesticide use. The Administration suggests that this should provide "incentives" for the development of safer alternatives. CU thinks that's wishful thinking. It is unrealistic to expect pesticide manufacturers to bear the primary burden of research to develop non-chemical pest controls and Integrated Pest Management approaches. The transition from intensive use of pesticides to IPM will require major research commitments by Federal and state governments, universities, and other actors who are not part of the pesticide-regulatory process.

The National Research Council report, "Alternative Agricul-

ture," envisioned a future in which chemically-intensive farming would be largely replaced by equally productive but more ecologically sound techniques, and outlined the policy changes the transition to such a future will require. But the future envisioned by the President's Food Safety Plan seems a carbon-copy of the present, with a regulatory system designed more to justify continued acceptance of pesticide-intensive agriculture and its attendant risks to public health, than to create alternative and safer controls, or to teach farmers how to use them.

Throughout the tumultuous debates over pesticide safety of the past year, CU has hoped that 1989 would be a turning point, a time when our society finally committed itself to produce our food with minimal damage to our health and the environment. The President's response is essentially to offer more "business as usual." Congress must go beyond the President's limited vision, and begin to chart the path to that better future we all know we can and must achieve.

Timetables

To end on a prosaic note, the President's plan is vague on details, such as the timetables to be established for decisions the EPA must make. S. 722 sets deadlines for most EPA actions, but as CU pointed out in our May 31 testimony, those deadlines probably will not work as intended. Whatever approach Congress ultimately adopts for EPA to follow, it must include realistic,

workable, firm deadlines to ensure that the process proceeds as intended.

What Makes a Risk Acceptable?

Our May 31 testimony addressed some of the non-biological dimensions of risk that need to be considered by Congress when defining acceptable risk levels from pesticides. In particular, we examined the moral character of risks, which explains why the public may be more concerned about a risk of one in 100,000 from a pesticide residue than they are about a risk of the same size or greater from a natural food contaminant like aflatoxin. Time does not permit me to go into those issues here, but I do call attention to our previous testimony on these points.

Thank you, and I will be happy to answer questions.

TESTIMONY OF CONSUMERS UNION OF U.S., INC.
ON H.R. 1725, THE FOOD SAFETY AMENDMENTS OF 1989

BEFORE THE SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT
OF THE COMMITTEE ON ENERGY AND COMMERCE,
U.S. HOUSE OF REPRESENTATIVES

prepared by:

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May 31, 1989

Mr. Chairman, Members of the Committee: My name is Ned Groth, and I am Associate Technical Director of Consumers Union,* in Mount Vernon, NY. I am here today basically to support H.R. 1725, although we do have some important reservations about the bill. Overall, CU believes passage of this legislation will both increase the safety of our nation's food supply and help to restore public confidence in that safety, which has been badly shaken by recent events.

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* Consumers Union is a nonprofit membership organization, chartered in 1936 under the laws of the State of New York to provide information, education and counsel about consumer goods and services and the management of family income. Consumers Union's income is derived solely from the sale of Consumer Reports, its other publications and films. Expenses of occasional public service efforts may be met, in part, by nonrestrictive, noncommercial grants and fees. In addition to reports on Consumers Union's own product testing, Consumer Reports, with approximately 4 million circulation, regularly carries articles on health, product safety, marketplace economics and regulatory actions which affect consumer welfare. Many of these articles relate to the safety of foods and other household products. Consumers Union's publications carry no advertising and receive no commercial support.

(1) Importance of The Pesticide Residue Problem

Even without the media-intensive events of recent months, such as the Alar debate and the NRDC's report on the hazards of pesticide residuess in children's diets, the subject of pesticides in foods would be a major public health concern and an important national policy issue for Congress to address.

Public opinion polls in recent years have repeatedly shown that consumers are very concerned about food safety. When asked about specific food-related health risks, a large majority of consumers say they think pesticide residues pose big, important hazards. Regardless of the existence of other food safety problems that experts say pose graver risks (such as microbiological contamination), consumers clearly believe risks from pesticides in foods are a significant problem, and want their government to solve it. Moreover, when asked whether the problem is getting worse or better, and whether the government is doing enough about it, consumers say the problem is worsening, and they want government to manage these risks more aggressively.

Various industry and government experts, especially in the past few weeks, have asserted that the public misperceives the risks from pesticide residues -- that the risks are minuscule, and far less significant than many other risks. One popular view, associated most prominently with U.C.-Berkeley Biochemist Bruce Ames, claims that natural carcinogens in foods produce the overwhelming majority of dietary cancer risk, and that the risks

of synthetic pesticide residues are trivial by comparison (see Exhibit 1). Such efforts to trivialize the issue usually are accompanied by suggestions that enough is being done to manage the risks from pesticide residues, and that the risks are justified by the economic benefits of the chemicals.

Consumers Union disagrees vigorously with that view. In a later section of this testimony, we will comment specifically on Dr. Ames' theory, which we regard as scientifically speculative and morally insensitive (see Section 5). More generally, CU believes there are solid scientific, ethical, and public policy reasons to make pesticide residues in foods a major concern.

The mass of existing scientific evidence shows clearly that pesticides are toxic; that several dozen of the hundreds now in use cause cancer in animal tests; that residues persist in some foods and are present in some populations' diets at levels high enough to pose significant theoretical cancer risks, as well as risks of other effects.

Authoritative scientific assessments by the EPA and the National Research Council agree that pesticide residues pose a substantial public health risk. The EPA, in its 1988 report, "EPA's Unfinished Business," ranked the problems it is charged with solving according to priority. Pesticides in foods was in the group of problems given highest priority -- those judged to pose "overall high/medium risks." Only three other problems (out of the 21 that were ranked) were rated as high in priority;

none were ranked higher.

In a landmark 1987 report (Regulating Pesticides in Foods: The Delaney Paradox), which may indirectly have led to the introduction of H.R. 1725, the National Research Council also recognized the public health significance of pesticide residues in foods. That report suggested, with many necessary caveats, that the theoretical cancer risk from pesticide residues could be, under some "worst-case" assumptions, as large as 20,000 cancer cases per year in the U.S. population. Even if the true risk is much smaller than that, this still is a public health concern of major magnitude.

Scientific uncertainty makes the actual size of risks from pesticides in foods highly debatable, and such debates will not be resolved soon. But risks have important components other than their size. Whether a risk is acceptable is a value judgment, which depends on such factors as the ethical dimensions of the risk. In CU's judgment, defining an acceptable level of risk from pesticides in foods is primarily an ethical exercise, more than a scientific one. We will address the ethical aspect of H.R. 1725 in Section (3) of our comments.

The NAS report cited above (The Delaney Paradox) was focused primarily on ways to improve the management of dietary pesticide risks. Regardless of how severe one believes the hazards from pesticides in the diet may be, there is near-universal agreement that Federal regulatory policies toward pesticide residues are

inconsistent, that decision-making processes are cumbersome and slow, and that improvements in this risk-management system are urgently needed.

In summary, there is an expert consensus that pesticide residues in the diet may pose a comparatively large risk, among all the risks that EPA manages, and are a high priority among environmental health problems. This risk is also significant for ethical reasons; food safety is more than just a scientific concern. And the way the Federal government manages pesticide-residue risks is widely seen as needing improvement. For all of these reasons, CU believes the subject matter of H.R. 1725 is as important and timely an environmental topic as any of the past decade.

Sections 2 and 3 of our comments focus on key provisions of H.R. 1725, in particular its definition of "negligible" risk. In Section 4, we comment on certain details of the proposed law, highlighting some provisions we support and suggesting improvements in other sections, such as the timetable for implementation of the Amendments, and the rules on confidentiality of data. Section 5 addresses the issue of comparative risks, and examines critically the claim that naturally-occurring carcinogens in foods pose risks thousands of times greater than those from synthetic pesticide residues. Our final section addresses the need for focused research to improve methods for assessing certain data in making pesticide regulatory decisions.

(2) "Risk-Based Standards" vs. "Risk/Benefit" Approaches

Some public comments about H.R. 1725 describe it as imposing a "risk-based standard." Such descriptions imply that the bill requires pesticide tolerances to be based solely on health criteria, without considering the benefits derived from pesticide uses on foods. As an abstract principle, CU supports that idea, which is the basis for key sections of the Clean Air Act and the Safe Drinking Water Act, among others. Defining safety and estimating the costs of attaining it are separate tasks, and what is "safe" should not vary from one decision to the next, depending on the benefits of the particular chemical.

Technically speaking, H.R. 1725 would make the size of the risk the one factor that determined tolerance levels for pesticide residues in foods. However, as CU reads the bill, it does not exclude consideration of benefits. More precisely, it implicitly recognizes the existence of benefits, and expresses a judgment by Congress of the level of risk to public health that is acceptable in return for those benefits. That level, in the case of cancer, is a risk of one cancer per million people.

CU believes the perception that H.R. 1725 would force EPA to "ignore the benefits of pesticide use" is inaccurate, and could distort public debate over the bill. We believe a more accurate statement is that H.R. 1725 establishes as national policy that no matter how large or small the benefits of using pesticides in food production may be, the risks associated with residues in

the diet shall not exceed "negligible," as defined by statute. We hope that perception can be clearly articulated, to focus debate on the key issue of the bill, its definition of "negligible" (i.e., acceptable) risk.

We believe a uniform statutory definition of "acceptable risk" would be very helpful. The alternative is ad hoc risk/benefit judgments on individual substances, which can produce inconsistent, widely divergent decisions in different cases. Such results make the regulatory process both unpredictable and seemingly illogical. A clear definition of "safe enough," from the Congress, should make the process more comprehensible and credible to regulated parties and to the consuming public. We applaud you for taking this step.

We also believe that H.R. 1725 doesn't really preclude EPA from making risk/benefit trade-offs, and in some respects, it would actually require it. Sections 5 and 6 of the bill require the Agency to regulate the aggregate risks of, respectively, one pesticide in all food items that contain it, and all pesticides residues in one food item. In each case, the Administrator must revoke tolerances or exemptions as necessary to ensure that the total risk is no more than negligible. This gives the EPA wide discretion to choose which tolerances/exemptions to revoke, and the Agency will probably use information on the relative risks and benefits of the individual uses when making those choices.

In summary, we believe that H.R. 1725 is in truth much more

imbued with "risk/benefit" approaches than some descriptions of the bill have suggested. Its general criterion for "negligible risk" implicitly considers benefits. And the law would require administrative actions that would almost certainly be based on risk/benefit judgments.

(3) What Is A "Negligible" (or "Acceptable") Risk From Pesticide Residues in The Diet, And Why Is It Acceptable?

As we have already stated, CU believes a central issue in H.R. 1725 is its definition of a "negligible" risk. We equate that with a definition of the level of risk that is acceptable in return for the benefits of pesticide use in food production.

H.R. 1725 establishes two criteria for "negligible risk." One defines "negligible" for effects which current scientific knowledge indicates have response thresholds at low doses, as the risk associated with a dose 1/100 of the dose shown to have has no observable adverse effect in animal tests. The other definition applies to risks that are believed to have no dose-response threshold, such as cancer. It defines "negligible" as a risk of one adverse effect (for instance, one cancer case) per million exposed people.

CU supports both of these definitions. We believe both are appropriate for this specific category of environmental hazard. Our reasons are detailed in this section.

(a) The 100-fold safety factor. For effects believed to have thresholds, H.R. 1725 establishes a 100-fold "margin of

safety" below the no observable effect level for the most sensitive toxic effect in animal experiments. This provision would incorporate in the statute an informal "rule of thumb" used by toxicologists in tolerance-setting. The factor of 100 is based on "prudence," rather than precise scientific knowledge. It is actually a combination of two 10-fold safety factors, each with its own rationale. One concern is uncertainty in extrapolating from animal data to humans, and the possibility that humans may be more sensitive to some toxic effects than rodents are. The other concern is the expected wide variation in human exposure and individual sensitivity to harm. It is considered "prudent" to allow a 10-fold margin of safety for each aspect.

CU supports the incorporation of this criterion in the law. While this unwritten "rule" has existed for many years, it has been widely violated in tolerance-setting. In our experience, many tolerances are based on residue levels found in field tests to remain when pesticides are applied at the maximum beneficial rate. If such residues exceed 1/100 of the minimum toxic level, the goal of a 100-fold safety factor has often been compromised, rather than restrict economically effective uses of a pesticide. When multiple tolerances are involved, the "margin of safety" can vanish entirely. For example, the EPA estimated a few years ago that the theoretical maximum residue contribution (dietary exposure that would occur if all foods for which tolerances had been set contained a compound at the tolerance level) for the

fungicides Captan and Folpet exceeded the maximum permissible intake by wide margins. These compounds were registered for use on so many foods that the tolerance structure provided no theoretical safety margin at all; instead, it allowed a fairly wide margin of theoretical hazard. (EPA recently proposed cancelling some uses of Captan, to reduce that theoretical hazard.)

To ensure that an appropriate safety margin is incorporated in tolerances, CU believes the statute should require it.

(b) The 1-per-million criterion. For effects believed to have no threshold, such as cancer, the bill defines a risk of less than 1 per million as "negligible." CU strongly supports this definition of "negligible risk," which we also consider a definition of acceptable risk from pesticide residues.

Before commenting on the "correctness" of the 1-per-million criterion, we must note that H.R. 1725 applies this standard in three different contexts: The risk from a single pesticide in a single food; the aggregate risk from one pesticide in all foods in which residues are permitted; and the risk from all pesticide residues that may be present in a single food. The bill would require, at different points in time, that neither the risk from a single tolerance, the risk from a single chemical in all of its food uses, nor the risk from residues in a single food item, could exceed "negligible."

H.R. 1725 does not address a larger issue, the acceptable level of total risk from all pesticide residues in the diet. We

believe that is a significant omission. Obviously, even if the risk from each individual food item and individual chemical were "negligible," the aggregate risk from all chemicals in all foods could be considerably greater than "negligible."

CU urges Congress to address this larger issue, and to state at least as a long-term goal what it judges to be the acceptable total risk from pesticide residues in the diet as a whole. In our judgment, setting a ceiling on risks from single chemicals and individual foods does not completely "solve" the pesticide problem. Total risk from pesticides in the diet is the "bottom line" for society. We urge Congress to place an appropriate ceiling on that total risk, as well as to set limits for the risks addressed by H.R. 1725.

Why is a risk of 1 per million acceptable? Scientific evidence and risk assessments can define the nature and size of a risk to health, within wide boundaries of uncertainty. But determining whether a risk of a given size is acceptable calls for a value judgment, beyond the realm of science.

CU believes that a risk of one cancer per million exposed consumers is reasonable for society to accept in exchange for the benefits of pesticides used in food production. We think risks larger than one per million, from this category of environmental contaminants, should not be accepted. The rest of this section explains the basis for our value judgment on this issue, the central issue of H.R. 1725.

A cancer risk of one per million is relatively small, when compared to certain other risks of everyday life. (See comments on comparative risks, in Section 5, below.) But a risk has many dimensions beyond its size. The aspects of a risk that are most critical in determining its acceptability are ethical dimensions and moral implications, not how large the risk is.

A large body of scientific evidence, collected in the past 20 years, solidly documents the importance of ethical and moral perceptions of risks. The science, here, is social psychology, not toxicology. These risk characteristics are every bit as well established--through repeated, reproducible scientific experiments--as carcinogenicity, mutagenicity and other biological components of risk. Two papers from the extensive literature on perception of risk are attached (Exhibits 2 and 3).

Many toxicologists and risk managers decry public concern with non-biological components of risk, which they consider "irrational." In CU's judgment, however, psychological and moral dimensions of risks are just as valid and important as the biological ones. Moreover, the former, not the latter, hold the key to whether society will accept the risk. They are certainly not "irrational;" but to ignore these dimensions of risks -- as many experts urge -- certainly would be.

With that preface, here are CU's reasons for concluding that a cancer risk of 1 per million is the appropriate level of risk for society to accept in return for benefits of pesticide use:

(i) The dread nature of the risks. Cancer is a particularly unpleasant disease. The presence of carcinogens in foods is, in our judgment, a more serious problem than the presence of toxic residues that pose other, less life-threatening hazards. It is in part because cancer is such a serious outcome that we believe the acceptable level of risk from pesticide residues in the diet should be no higher than 1 in a million.

(ii) The special moral status of food. Like air and water, food is something everyone needs, and cannot do without. There are significant moral differences between toxic residues in food and toxic residues in products that consumers can easily avoid. In CU's judgment, such distinctions justify strict standards for acceptability of toxic hazards in foods.

(iii) The involuntary nature of exposure. Consumers have a choice, more or less, when it comes to the risk of smoking cigarettes, driving a car, or living in a radon-contaminated house. We have no such choice with respect to pesticide residues in our foods. Someone else's decision determines whether a pesticide is used, and those who will eat the treated food are not asked to consent to the decision. When consumers are given a choice, they almost always choose to avoid even the theoretical risk associated with a possibly carcinogenic pesticide residue in their foods. (Consumers Union has never been as swamped with consumer inquiries as we were with calls asking us which brands of apple juice had the lowest Alar levels.) Because the risks

of pesticide residues are involuntary, they are far more offensive, morally, than other, even larger, voluntary risks. In our judgment, minimizing moral outrage over risks is a legitimate aim of public policy, and a valid reason to define risks above one in a million from these contaminants as unacceptable.

(iv) Lack of consumer control over risks. When driving a car or drinking alcohol, consumers can control their exposure to risk, to at least some degree. But pesticide residues in foods are invisible. Consumers can't tell if they are there; if some are present, they frequently cannot be removed. There is very little consumers can do to avoid these risks. The availability of "organically grown" fruits and vegetables, which in theory contain no residues, is restricted by the limited supplies and comparatively high cost of such produce. CU finds a risk that is hard to detect and harder to avoid less acceptable, morally, than risks more readily managed by individual actions.

(v) Many of the risks are unnecessary. There are alternatives to most pesticide uses, ranging from non-chemical controls or integrated pest management to no treatment, and accepting a higher rate of pest damage to food. Each alternative has its own set of costs, risks, and benefits. But consumers know there are choices. Carcinogenic pesticides do not need to be used on foods, if we are willing to accept the costs of doing without. In CU's judgment, this fact argues for accepting no more than a risk of 1 per million from pesticide residues.

(vi) Technological risks differ from natural risks. Later in these comments (see Section 5), we will assess the scientific credibility of the claim that cancer risks from naturally-occurring toxic substances in foods vastly outweigh the risks from synthetic pesticides. In judging the acceptability of each type of risk, however, practical and moral distinctions between the two types are critical.

In practical terms, natural carcinogens in foods can be and are controlled, when they pose significant risks (aflatoxin is stringently regulated, for instance). The main difference between natural and synthetic carcinogens in this context is that society can, if it needs to do so to keep risk to an acceptable level, forbid the use of a pesticide, a step we can't take with natural substances like aflatoxin.

There are also important moral distinctions between risks from natural and synthetic toxins in foods. A popular phrase these days is, "Nature is not benign." CU's retort is, "True, but She is blameless." Consumers hold people who use pesticides responsible for ensuring that the risks of such uses are not unacceptably high. Nature cannot be similarly held morally accountable. For that reason, consumers are justifiably more outraged at hazards from synthetic pesticides, and in CU's view are justified in demanding that those risks be kept to a very low level.

(vii) The distribution of risks and benefits is inequitable.

Pesticide uses on foods have important benefits for consumers. They make food more attractive, more abundant, more consistently available, and sometimes--not always--more affordable. But the most direct beneficiaries of pesticide use are agribusiness and chemical companies. Most consumers have never been asked what value they place on cosmetically appealing, abundant food, or how much risk they would accept in return for those benefits. Many consumers perceive that someone else is benefitting economically they are exposed to risk--a perception that fuels outrage, especially when they are told it's for their own good.

In CU's judgment, the distribution of benefits and risks from pesticides used on foods is inequitable, which further supports the need to define "acceptable" risk as no greater than one per million.

For all of these reasons, CU judges a cancer risk of one per million people acceptable, in exchange for benefits of pesticide use. But we must stress that this criterion for acceptability is specific to pesticide-residue risks. For other hazards with different ethical attributes (e.g., radon), a larger risk may be acceptable. For still other risks, such as dioxin residues in human breast milk, a risk of one per million is far higher than we consider "acceptable." But our considered judgment is that one per million is the "right" criterion for pesticides in the diet.

(4) Comments on Specific Provisions of H.R. 1725

CU has comments on several specific sections of the bill, some of which we support, and some of which we find difficult to accept in their current form. In the latter cases, we suggest modifications that we believe would strengthen the bill.

(a) Inert ingredients [Section 408 (a)(2)]. We strongly support the extension of tolerance provisions to inert ingredients. EPA has already recognized its need to deal with inert ingredients under FIFRA, and a statutory requirement to do so in tolerance--setting is highly appropriate. Many "inerts" are in fact very toxic, and some are carcinogenic, even though they are not used in products as active pesticide ingredients.

(b) Substances with no detectable residue [Section 408 (a)(4)]. The bill requires that tolerances for chemicals that leave no detectable residues shall be set at the lowest level that is detectable using available test methods. CU opposes that approach. There is no basis for assuming that the lowest detectable level is the same as, or lower than, a level that poses a "negligible" risk. If current practical test methods cannot detect a residue, the tolerance should be set at "no detectable amount." Then, if analytical methodology subsequently improved so that levels could be detected that posed less than a negligible risk, a tolerance within the detectable range could be established.

(c) Application of the Negligible Risk Standard [Section 408 (b)(2)(A)]. CU strongly endorses the provision that tolerances should be set to protect population groups "with special food consumption patterns," such as infants and other children. We urge that language be added to the bill extending protection as well to "population groups who, because of special physiological conditions, can be identified as especially susceptible to toxic effects (such as pregnant women or the elderly.)" Although the language of the bill elsewhere mentions "populations at greatest risk" and "an ample margin of safety" (considering) "variability of individual sensitivities and the sensitivities of population subgroups," the two populations just noted may warrant specific mention. Neurotoxic effects are an especially critical concern during the last trimester of pregnancy, when the brain develops rapidly. Chronic toxic effects on various organs that decline in function with normal aging may be especially significant for the elderly consumer.

(d) Exposure assessment [Section 408 (b)(2)(C)]. CU strongly supports the approach spelled out in the bill, which requires an assessment of total dietary exposure (including drinking water) when establishing a tolerance for a single food. This approach is essential to preclude the situation described in our comments on pages 9-10 above, in which the summed exposure from multiple food items for certain fungicides, in theory at least, greatly exceeded a safe level.

We strongly support the approach in Section 408 (b)(2)(C)(ii)(II) which requires that, if actual residues are much lower than tolerance levels, the tolerance should be lowered to match the actual residues, rather than left unrealistically high.

(e) Practical methods of analysis [Section 408 (b)(2)(E)]. In CU's judgment, this is a very important provision of the bill, and we support it. It says that no pesticide residue may legally be present in foods (no tolerances may be established) unless there is a practical method that can be used (by the FDA) to detect and measure the residue at the tolerance level. This should provide incentives to develop practical test methods.

We do have one reservation about the wording of the requirement. Paragraph (i) of the section states that, to be approved, a method must be the "best available practical method" (emphasis added). In our judgment, forcing a choice of a single "best" method seems inhibitive. A performance criterion (e.g., "Must be able to reliably and reproducibly identify and quantify the residue at a level no more than one-tenth of the tolerance level"), would allow more flexibility in meeting the goals of the statute, in our judgment.

In CU's judgment, EPA must be able to set tolerances at the levels needed to protect public health. If enforcement of those tolerances requires improvements in the FDA's analytical capabilities or resources, such improvements must be achieved. The analytical resource should be as large and as advanced as needed

to protect public health; it should not be a brake on effective public health protection. The wording here, which requires that there must be a "practical" method, one that FDA can routinely perform with resources available to it, seems appropriate, as long as it is enforced by the provisions of Section 11 of the bill. (Section 11 requires that tolerances be revoked within three years if a practical analytical method to detect the residue at the tolerance level does not exist.) We would stress, however, that without Section 11, we fear the provisions of Section 408 (b)(2)(E) could allow the lack of practical analytical methods, and/or lack of FDA resources to develop better methods, to inhibit the EPA's tolerance-setting activity.

CU also supports the provision for single-residue methods, in Section 408 (b)(2)(E)(ii). It is a reality of pesticide chemistry that not every economically important compound can be detected using multi-residue methods. An important example of great current interest is Alar and its breakdown product UDMH, which require specific analyses. Some single-substance methods will likely always be needed. CU does question whether review of all single-residue methods every two years is sensible. Why not provide for review initiated by petition, whenever advances in analytical methodology merit a change?

(f) Revised Negligible Risk Standard (Section 6). Section 6 of the bill provides that, within 6 years of enactment of these amendments, a new standard for "negligible risk" would apply.

That new standard would require that the aggregate risk from all the permitted pesticide residues in a single food must meet the "negligible risk" criterion.

CU strongly supports this approach. For certain common and heavily-consumed food items, such as apples and tomatoes, more than 100 pesticides are currently registered for use. Among the compounds allowed on tomatoes, 23 are suspected carcinogens; 24 pesticides used on apples are in the same category. It is conceivable that even if every pesticide residue were kept below a tolerance consistent with a "negligible risk," the combined risk from these foods could be substantially greater than negligible.

In CU's judgment, public demand that pesticides in foods pose no unacceptable risks goes beyond a "one-substance-at-a-time" perspective. Especially where carcinogens are concerned, consumers want their foods to be safe, period. To meet that goal, the approach created in Section 6 seems essential.

However, we are deeply concerned that Section 6 appears to repeal the earlier provision that required tolerances to weigh exposure to a single pesticide in all foods on which it may be used, as well as drinking water. The new limits of Section 6 address aggregate risk along a different dimension; the control required by earlier sections would still be needed when Section 6's new limit took effect. We hope Congress does not intend to remove one important standard while imposing another. We urge that Section 6 add a new standard, not replace an old one.

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(g) Evaluation of existing residues (Section 5). In CU's judgment, this is an especially critical section of the bill, because of the overwhelming need to expeditiously and methodically review, and revise or revoke, current pesticide tolerances. The process of achieving "negligible risk" from pesticides in the diet cannot be allowed to stretch over decades, the same way the review of currently registered pesticides under FIFRA has dragged out. This bill must establish strict deadlines for the implementation of EPA's tolerance review.

The bill before us takes important steps to meet that goal, but CU believes the procedures it specifies need to be clarified and strengthened. We see weaknesses in the procedural scheme created by H.R. 1725, which could allow EPA to avoid meeting the deadlines Congress apparently intends the Agency to meet.

New Section 5 requires the Administrator of EPA to evaluate existing toxicity and residue data for all current tolerances within 90 days of the enactment of the bill, and to determine whether each residue is likely to pose a greater-than-negligible risk. The Section then establishes three procedural "tracks," depending on the outcome of the Administrator's initial evaluation.

One track applies if EPA determines that a tolerance exceeds the negligible risk standard, but that the risk is not "significantly" greater than negligible, and that the Agency needs more information before it set a new tolerance that would pose only a

negligible risk. We will call this "Track A."

(We will digress for a moment to note that "significantly," in this context, is undefined. CU believes Congress should put some limit on Agency discretion, by specifying the threshold of "significantly greater than negligible.")

The second procedural track created by Section 5 applies if the Agency determines that it needs more information before it can determine whether a residue may exceed the negligible risk standard. We will call this "Track B."

A third track applies when the Agency determines that the risk from a residue may exceed "negligible." We will call this "Track C."

Track A. In following Track A, EPA must determine:

- That it has sufficient data to determine that dietary exposure to a pesticide residue presents a risk that is greater than negligible;
- That the risk presented by the residue is not significantly greater than negligible;
- That more data is needed to support the continuation of the tolerance; and
- That the Administrator intends to issue a subsection (b)(1)(B) notice for the residue.

If the above conditions are met, the Administrator must initiate the "special data requirements" procedure in new Section 408 (f)(2), within 30 days of making the determination.

Although there appear to be strict guidelines that would require the Administrator to review existing data, make determinations on the three criteria, and initiate action under Section 408 (f)(2) within 120 days of enactment, as we read the bill the language does not clearly establish the deadlines.

For example, the 90-day deadline applies only to the evaluation of existing toxicity and residue data, and to the Agency's determination that residues may pose risks that are greater than negligible. The 30-day deadline applies only if the agency has determined that additional data are needed and that dietary risk is not significantly greater than negligible. There is no requirement that the Agency make these latter two determinations within the 90-day period. No deadline is established for these two decisions, which means that there could be an indefinite delay before the Agency inititated Section 408 (f)(2) procedures. Until the Administrator determined that the criteria for subsection (b)(1)(B) had been met, the notice seeking further data would not be issued, and the regulatory process would be at a standstill.

Track B. To follow Track B, EPA must determine only that it has insufficient data to determine whether dietary exposure to a residue poses a risk greater than negligible. Once this determination is made, the Administrator must initiate action under Section 408 (f)(2). Since that determination must be made within 90 days of enactment, there are clear and adequate dead-

lines in the bill for cases that follow this track.

Track C. To follow Track C, EPA must determine:

o That a residue may pose a risk greater than negligible.

Cases that follow Track C could include two subsets: Those in which the risk from a residue was determined to be "not significantly greater than negligible," as in Track A; and those in which the risk was determined to be "significantly greater than negligible."

As we noted for Track A, there is no deadline in the bill specifying how long the Agency has to determine whether a given residue poses a risk that is or is not "significantly greater than negligible." Nor is there a deadline for EPA to decide that it does not need further information. There thus appear to be no deadlines that would force EPA to proceed onto Track C for residues that meet these criteria.

If EPA should determine that a residue poses a risk greater than negligible, but not significantly greater, it must issue a notice under paragraph 2 and begin procedures described in paragraph 3. But there are no deadlines for the issuance of this notice. Since all timetables for subesquent data submissions and decisions are triggered by the issuance of the paragraph 2 notice, the lack of a deadline here is a major flaw.

In conclusion, although H.R. 1725 would clearly prevent EPA from granting new tolerances that pose greater than negligible risks, it is much less clear that it can achieve its goal of

reducing to negligible the risks allowed by current tolerances. Clear and enforceable statutory deadlines for each intermediate step toward this goal are needed to attain the goal.

We recommend the following amendments, to strengthen these Sections of the bill:

- Add language to Section 5 (a)(1) requiring the Administrator to perform within 90 days of enactment all tasks required to make the determinations that trigger the 30-day deadlines in paragraphs (2) and (3).
- Establish a deadline for determinations required under subsection 5(b).
- Establish clear deadlines by which the Agency must initiate the actions rquired under subsection 5(b), i.e., initiate a 408 (e) proceeding or issue a paragraph (2) notice.

Section 5 should also be amended to ensure that the public can effectively monitor EPA's progress in evaluating hundreds of existing tolerances. EPA should be required to publish its determinations under subsections 5(a) and 5(b). The public has a right to know and a large interest in knowing how much risk a pesticide residue poses or may pose, whether EPA has enough data to make that determination, and even whether EPA has determined that it has enough data. When EPA determines that a residue poses a negligible risk, or a risk not significantly greater than negligible, the information on which that judgment was based should be made public. The basis for EPA's judgment that

it needs more data should also be public.

(h) Confidentiality of data [Section 408(h)]. New Section 408(h) provides cumbersome, lengthy procedures through which a party seeking information related to a tolerance proceeding must pass in order to obtain that data. In CU's judgment, the effect of these procedures will be to severely restrict the public's access to health and safety data. We see nothing proprietary in data concerning the uses, residue levels, or possible toxicity of pesticides in foods, and no justification whatsoever for data EPA has that bear on important matters of consumer health and safety to be kept secret. Only bona fide trade secrets, such as product formulations, should be concealed from public scrutiny.

We urge you to remove the restrictive procedural rules that require inordinate time to be expended by persons seeking access to data, and limit the form of access allowed. All those rules accomplish is to ensure that very few members of the public can ever expect to actually see the data.

(5) Some Perspectives on Comparative Risks

In recent public debate over the hazards of pesticides in foods, industry and others frequently compare risks of pesticide residues with other hazards of life. They point out that many other risks appear, based on the best current data, to be much larger than the risks of pesticide residues. By most signs, the public is more willing to accept many comparatively larger risks than it is to accept the risks from pesticide residues. (There is neither evidence of great public alarm nor concerted media and political campaigns aimed at, for instance, the risks from tobacco, alcohol abuse, radon in homes, or automobile crashes.)

Many pundits and experts therefore consider the public "irrational" to be so concerned about pesticides residues. They argue that, since resources are limited, Congress (and others, such as the media) should concentrate on the biggest risks, and not waste time and energy trying to reduce already small hazards.

While there is a certain logic to that argument, it is too one-dimensionally utilitarian. How important a risk is depends on more than how many people it will kill; it also depends on how offensive it is, in moral and ethical terms. When such moral dimensions are considered, public response to risks does not appear irrational at all. Most of the larger risks that society tolerates are morally acceptable, because they generally involve individual freedom of choice, equitable distribution of risks and benefits, and other attributes that reduce their capa-

city to provoke public outrage. Most of the small risks that people worry intensely about and demand to have reduced possess ethical attributes that provoke outrage, as pesticide residues do (see pages 13-16, above).

CU believes society must reduce both types of risks--those that are highly likely to kill people, and those that are highly outrageous to American moral sensibilities.

One important subdebate of the "comparative risk" argument involves the relative contribution to dietary cancer risk of naturally-occurring toxic substances in foods, compared with synthetic pesticide residues. This issue has been raised most directly by the work of Bruce Ames, from the Department of Biochemistry at the University of California at Berkeley. One of Dr. Ames' major published papers on the topic, and a shorter popular version, are attached as Exhibit 1.

Ames has said that we are exposed to "10,000 times as much" natural carcinogens in foods as we are to carcinogenic synthetic pesticide residues. That point has been used by others, in various contexts, as a basis for claiming that "99.99 percent of dietary cancer risk comes from natural substances." Since there is no evident cancer epidemic attributed to natural carcinogens in the diet, the implication is that pesticide risks must be truly de minimus.

CU believes that argument is wrong. It is scientifically wrong, because neither Bruce Ames nor his followers has a valid

scientific basis for making the assertions they make. It is morally wrong, as well, because it ignores all the ethical and value dimensions of pesticide risks, which make the risks less acceptable to society than most other risks, regardless of how large the risks may actually be.

We have addressed the moral dimensions of pesticide risks in Section 3 of these comments, and will not repeat that analysis, save to stress that we believe the moral issues are the dominant ones public policy must consider. Here, we will focus on the scientific weakness of the argument that natural cancer hazards in the diet overwhelm those from synthetic pesticides.

In plain terms, the Ames theory is speculation. It is an interesting hypothesis, based on a small number of data points. But the vast majority of information needed to make quantitative comparisons between natural and synthetic carcinogens in foods simply does not exist. Dr. Ames and his followers have extrapolated from a very few data to reach sweeping conclusions, which are opinions, not facts. The argument may seem credible because of Dr. Ames's stature as a scientist at one of the nation's top universities. But in our judgment, it is somewhat reckless to assert that public policy should be based on a hypothesis for which there is as yet so little concrete scientific evidence.

The evidence that does exist is also highly uncertain, and thus debatable. There are only about 50 naturally-occurring toxic substances in foods that have been adequately tested for

carcinogenicity, and about 20 are known carcinogens. Among the synthetic pesticides, perhaps one-half of the more than 300 chemicals used on foods have been tested in animal experiments, and over 60 of those have shown some degree of carcinogenicity. But the vast majority of natural substances--and about half of the synthetic pesticides--have not been tested. We do not know how many of them are carcinogens. Ames is assuming that, if all natural toxins were tested, roughly the same fraction (about 40 percent) would turn out to be carcinogenic as has been the case for those already tested--a speculation which could very well be untrue, for many reasons.

A second critical issue is the comparative potency of both natural and synthetic carcinogens in the diet. Some natural carcinogens (such as aflatoxin) are extremely potent. Some of the synthetic pesticides are much less potent carcinogens. But there are also very potent carcinogens among synthetics, and carcinogens of low potency among the natural compounds. Ames and others are fond of comparing a single pesticide (such as EDB or DDT) with a single natural carcinogen, such as aflatoxin or dimethylnitrosamine. In each of these cases, the natural substances are far more potent. But to imply that this is always or typically true is grossly misleading, especially when there is far too little data to estimate accurately the potency of most carcinogens in either group.

A third area in which Ames' analysis is flawed is that it

generally compares risks from single substances, e.g., "The risk from eating a peanut butter sandwich is 18 times as great as the risk from drinking a glass of apple juice." That comparison, in the context of the Alar debate, focused on the risk from just one substance in apple juice, UDMH, the carcinogenic breakdown product of Alar. But there are 24 carcinogenic pesticides now registered for use on apples. Such comparisons are woefully incomplete and misleading.

The final critical weakness of the Ames argument is in its assessment of exposures. The presence of carcinogens in foods alone is not enough to define the risk; one also needs to know which foods contain it, what the residue levels are, and most important of all, how much people eat of the foods that contain the carcinogen. The data needed to estimate actual exposures are generally not available. There are too few residue data to define typical levels of either natural or synthetic carcinogens in most foods, and very little definite can be said about the amount of mushrooms or Brussels sprouts, for instance, that are consumed by most population groups. In order to estimate comparative risks, Ames and colleagues have used whatever data are available, and made assumptions where there are no data. The reliability and validity of the data and assumptions in most cases are open to challenge, to say the least.

In summary, when all the weaknesses in the scientific data on which Ames' estimates rest are examined, the comparative risk

information he has generated can be seen for what it is: Extraordinarily tentative, uncertain information, subject to extreme uncertainty. When other scientists have applied Ames's methods to some of the same data, they found that some natural and some synthetic carcinogens pose risks of about the same size. (See Exhibit 4, attached.) While this subject surely needs continued research, the information available now is too fragmentary to provide any sound guidance for public policy. And people who cite this work as if it were fact are doing a disservice to the public's understanding of regulatory priorities.

(6) Some Research Needs

While the passage of H.R. 1725 would simplify EPA's tasks in setting pesticide tolerances in some respects, it would not end controversy over what is a "safe" level of a given residue. The argument would merely be shifted onto whether EPA had used the "correct" assumptions and data in doing its risk assessment, in order to determine whether a given residue posed a risk greater than negligible.

Risk assessment, while heavily based in science, is more an art than a science. There is no current agreed-upon definition of "great art;" that is, different risk assessors, using all the same data, could come out with quite different results when assessing the same risk, because of different assumptions and judgments the assessor must make at many points in the process.

Because of the possibility of vigorous disagreement over how particular risk assessments are conducted as EPA struggles to implement the mandates of H.R. 1725, CU believes Congress could assist the Agency by seeking an authoritative statement of the current consensus about the best way to assess carcinogenic risk, perhaps from the National Academy of Sciences.

As much as the tool of risk assessment needs refining, the process of benefits assessment needs it more. In our judgment, EPA's benefits assessments for pesticide decisions have in the past often tended to be arbitrary and simplistic. Since there is certain to be a major component of benefits assessment in the Agency's decision-making for the foreseeable future, we urge you to require that assessments of benefits be as rigorous and as subject to peer review as risk assessments currently are. Here too, an authoritative report from the NAS on the "state of the art" of benefits assessment could be very useful.

The CHAIRMAN. Thank you very much.

Just a few general questions. We have previously heard the National Academy of Science evaluation of what the current negligible risk standard is over at EPA. Would any of you like to make a judgment of EPA's current standard?

Ms. HATHAWAY. Well, I will just pitch in. The National Academy of Sciences looked at the legal tolerance level, the absolute maximum levels of exposure, and from those levels of exposure the cancer risk would really be astronomical.

EPA and others have countered by saying, "Well, in fact, the residue levels are somewhat below and sometimes substantially below the legal limits." But no one really has good data on exactly where the residues are for many of these pesticides.

What we do know is that for the eight pesticides that NRDC studied, that are cancer-causing, that are used in food, we looked at actual residue levels and we found that the risk exceeded the 1 in a million standard 250-fold. So that shows us that just from eight of the 70 or so pesticides that cause cancer, we do have a real-world high risk and that something must be done to squeeze that risk down as far as possible and phase it out over time.

Mr. SCHULTZ. May I comment on that? As far as I can tell, to directly answer the question, the National Academy of Sciences is as correct as you can be, that EPA, when it applies risk assessment, is applying something between 1 in 100,000 and 1 in a million. This contrasts with the FDA, which applies 1 in a million across the board.

But the problem is in the vast majority of cases, EPA isn't applying anything. So most pesticides have never even gone through that kind of process.

Mr. GROTH. Senator, my understanding of EPA's policy on this is that as a theoretical target they use 1 in a million, they would try to apply that to say, drinking water or air, where there is no offsetting benefit. Under FIFRA, because it is a risk-benefit statute, I think that they accept risks up to 100,000 routinely, 1 in 100,000 routinely, and where th re are large offsetting benefits, they are willing to accept whatever risk the pesticide poses.

The CHAIRMAN. Are you able to make any judgment about the increased risk of cancer would be if we continue to use their standard?

Ms. HATHAWAY. We can just say that from the eight pesticides we were able to examine where there was good data on how much residue remains in food and there was good data on the consumption patterns that children experienced, that the risk from just those eight, just from preschool exposure, so exposure that one would have by age six, would lead to cancers up to 5,500 per year. And that is a fairly astounding number when you are thinking that this is just a very small subset of the total pesticides used in food.

Mr. GROTH. Senator, these are theoretical estimates based on models that are loaded with many, many assumptions. I think NRDC's analysis is certainly a scientifically respectable one. But the big issue about these risks is that it uncertain whether they are real or not, and the public simply doesn't want to take the risk. Risk is uncertainty, not knowing whether there is going to be a

cancer or not. And it is the possibility, not the actuality of those cancer deaths that frightens people.

So the issue is really not whether it would be 100 or 100,000 cancers but whether there should be any risk at all and whether people are willing to accept it.

The CHAIRMAN. Ms. Bloom?

Ms. BLOOM. We would just agree with Ned's comments.

The CHAIRMAN. Well, if you went to the zero risk standard by the year 2000, what is that going to mean both in terms of agribusiness and the cost of food?

Ms. HATHAWAY. Well, I think that it's very hard to predict because, in large part, our government has not looked at ways in which we could phase out or provide alternatives for dangerous pesticides. What the current pesticide law has done is justify risks and maintain the status quo.

What we do know the biggest problem of cancer risk is from is from the fungicides. About 90 percent of the pesticides that are used to combat mildew and mold are showing up as causing tumors in laboratory animals. So to phase out carcinogens would probably mean the removal of a lot of the fungicides, if not all the fungicides that we have traditionally relied on.

To do that we are going to have to explore alternatives. We are going to have to look at different ways of, for example, breeding better tomatoes that are resistant to certain fungal diseases. That is not something that may happen in the next year, but it is certainly something that we can anticipate occurring over time if we put a very concerted effort in our government to looking for those kinds of improvements.

But what we will certainly not have is any incentive for people to provide alternatives to these cheap and very plentiful fungicides if we condone their risks simply because they do have benefits to the food supply and to growers.

Mr. SCHULTZ. Senator, there are two ways to reduce risks, cancer risks in particular. One is to find a safer chemical, which I think the regulatory parties could be given some incentive to do under current law and under proposals.

But the other is to do more basic research about the biology of a pest and to find ways to control it without necessarily using chemicals. That approach is called integrated pest management, and it has been very popular in the biological community for about 20 years but it is getting essentially zero research support.

And the real answer, the long-term answer, is to develop alternatives to hazardous pesticides by putting USDA and the universities to work on research.

Ms. BLOOM. I would like to refer you to the National Academy of Sciences 'recent report called "Alternative Agriculture," which concludes from looking at a number of case studies, that it is quite feasible that we could phase out the use of most of the riskiest pesticides without any significant disruption to agriculture or food supply.

The CHAIRMAN. Let me just recognize Senator Adams.

Senator ADAMS. Thank you very much, Mr. Chairman.

The CHAIRMAN. Now, what guidance can you give us, to the committee? You know where I stand, obviously, with S. 722. I am

strongly in support of it. We have the administration's proposal, and a lot of pesticides that have effectively been grandfathered in prior to the enactment of the Delaney clause.This state of confusion and inconsistency is going to continue unless we pass new legislation. We have a pretty good indication of what is going to be acceptable and what is not acceptable to the administration. We are going to try to work with them.

We have started off with different positions before, on minimum wage and the Americans With Disabilities Act. And we have eventually been able to make some progress, important, very important progress, with the ADA, less so with the minimum wage.

We are again faced with different policy options, different variables. Give me some sense about the variables. What are the things that are intolerable in terms of policies and standard, relating to food safety and pesticide residues on foods? Give us some feel for that, if you would.

Ms. HATHAWAY. What I would say is essential is that we not erode the fundamental health-based nature of the food law.

The CHAIRMAN. That is number one.

Ms. HATHAWAY. The Food, Drug and Cosmetic Act, that is essential.

The CHAIRMAN. Yes.

Ms. HATHAWAY. We are better off with the current law than with something that would put risks, justify risks on the basis of some economic analysis.

The CHAIRMAN. Even with the pesticides that are currently allowed?

Ms. HATHAWAY. Well, I think so, because ultimately I think we are going to be successful in the courts if EPA does implement their so-called Delaney policy because I think it's flagrantly illegal. And so I think we are better off with the current law if we are going to have to sacrifice something like the basic health nature of the statute.

The other thing that I think is absolutely fundamental is that we keep some fail-safes to keep the Federal Government's pesticide program honest. And one of the most important fail-safes that we have had is the authority of States to act when the Federal Government is really becoming negligent in how they are handling the pesticide program.

It is very rare for a State to figure that it's worth their resources and their time and the battle with the Federal Government that is necessary in order to set a higher or more protective pesticide limit. But a few States have decided that it is worth doing so in the case of certain very dangerous pesticides like ethylene dibromide and Alar. And we need that kind of fail-safe because it does keep the Federal Government looking over their shoulder, feeling that they do have to be responsive to other scientists and they have to be able to justify the standards that they have set.

Top take away that power of the States to set more protective limits is not only going to infuriate States who do have a fundamental mission in protecting their citizens, but it is also going to make our own Federal Government more lax and a little bit more cocky about their ability to get away with not being aggressive in

their pesticide program. And that is certainly not the message we want to send.

Mr. SCHULTZ. There are two other points that I think are critical. One is the issue of benefits. As long as the agency can consider the benefit, the economic benefits to the industry and balance that against the health risk to the public, the health standard can be undercut immediately.

The second point, Senator Kennedy, is in your bill there are a number of timetables. It is not going to do any good to give EPA enforcement discretion, discretion to have higher fines and additional authority, unless the law also has some handle to require them to act. And so I think the timetables are very important to retain and to focus on.

Mr. GROTH. Senator, I endorse what Janet said about the State preemption issue. And I also feel that real center of this is the 1 in a million versus some higher definition of risk. We believe that 1 in a million is the highest level of risk that consumers will accept, and in many cases they won't even accept that risk because they feel there is no justification for it.

But whatever the individual risk size is defined to be, EPA must consider that in the context of the additive risk of multiple residues. It is not feasible to accept looking at one after another risk and just letting them add up to any total that they add up to.

The CHAIRMAN. We are joined at the hearing by Senator Adams and Senator Hatch. Obviously the support of Senator Hatch will be extremely important in this area as in other areas, to achieve the desired outcome.

Senator Hatch, I had just asked, as we are looking down the road, what are the issues where there might be some flexibility, and what are the issues which are absolute bottom line that can't be compromised.

If I am wrong now, tell me. The current standard of 1 in a million, would be better than the Bush proposal. Is that correct?

Ms. HATHAWAY. That's correct. Yes.

The CHAIRMAN. The second issue involves economic benefits weighed against risks given the track record over at EPA.

And then the third issue involves the question of State preemption. Many individuals argue that allowing States to enact their own food safety standard helps to keep EPA and FDA, particularly their scientists, on their toes in terms of new technology, new evaluations of risks.

And the fourth point, which I obviously should have known and didn't give it the kind of attention in my own thinking, is the fact of the risks with multiple pesticide residues, and the need for multiple tolerances.

And then of course, you mentioned vulnerable populations—particularly expectant mothers, children—that may have a different level of risk.

Mr. GROTH. Senator, if I could clarify that, it is shown by the NRDC report that because of the diets that children eat, which are very high in fruits and vegetables and fruit juices and things like that, you can get more than half of your lifetime risk by the time you're five years old. So if you calculate the risk by looking at the

average adult's diet, you are going to very seriously underestimate it.

The CHAIRMAN. Senator Hatch, Senator Adams has a scheduling conflict. He had wanted to make a brief comment.

Senator ADAMS. I thank you very much, Orrin, and, you, Mr. Chairman.

I am very much in support of the things which you are trying to do. I am not in favor of the administration approach. But I have some very deep concerns about what you are proposing because I come from an agricultural State as well as a very highly concentrated industrial State. So we have a great split within our grouping of people as to what should be done on this problem.

And we have just lived through two very, very hurtful effects on two different products involving both pesticides and systemic—you can't call Alar really a pesticide; it is a systemic reddener.

And so I would like to put my full statement in the record, Mr. Chairman.

The CHAIRMAN. Without objection, it will be included in the record.

Senator ADAMS. But I wanted to indicate the troubling aspects that I have and Senator Harkin has, Senator Matsunaga had, about the state of Federal regulation. And to show you how concerned, I have gone before the Agricultural Subcommittee, of which I am a member, of the Appropriations Committee, and obtained money for laboratories in the tri-city area and I have talked to the Washington State University and to their extension groups as well as to the Battelle Laboratories in that area, because we had both consumers and producers injured by the existing system. And I mean injured badly. And I want to give the example of Alar because a lot of people don't know what the other half of the Alar problem was, or the Alar damage.

We didn't have any advance warning. By we, I mean growers had heard that Alar might not be an appropriate product. So about 75 to 80 percent had gotten off of it, but you couldn't tell which 75 or 80 percent. They weren't sure and they hadn't had a government regulation.

What the system in the past has been was that you relied on a government regulation. And that is why I agree with Senator Kennedy that these hearings are so incredibly important. If you in effect got the stamp of approval, you went ahead and used it, you invested your money, you sent out your product, and that happened.

In the case of Alar, this had basically been done, and it was supposed to be all right. But what happened was that a number of groups such as yourself, properly so, and a number of other groups skipped over into the marketing area, which is what is going to happen in the United States now. That is why I consider this so important for both farm groups as well as consumer groups, is that with the new modern media you are moving out or you have moved aside entirely the regulatory group, either to give confidence or examination, because if you don't agree with what is done by the regulatory group you can stop the market.

And what happened with Alar was that 85 percent of the apples from the State of Washington had never seen Alar. But the word

went out that red delicious apples had been used with Alar and the sales stopped.

Now, that is a very powerful weapon and, I think, got everybody's attention. You will notice ads running now and you will notice statements on the television that say there is a new crop. And believe me, they are trying very hard among producer groups not to have anybody that has ever used Alar allowed. Alar was used for lower-altitude apples, those that are grown in warm areas and so on, because they turn red faster and they wouldn't stay yellow. In other words, you're going to get to see a lot of yellow and spotted apples from now on, which is fine by me. But I just want you to know that that is part of the effect of this.

The others in the higher areas, they didn't use the Alar, and they were saying ha-ha-ha until it came out that all apples were suspect, at which point both sides went down.

Now, I am very troubled, therefore, about the present state of this. I agree completely with Mr. Groth's comment. I think we have to have laboratories within these States that are giving information to growers, producers, as well as to consumers, because if we set the standard—and I am not for a risk-benefit standard like the President has suggested, because what happens is if you get a risk-benefit standard stated at one point along the way and that turns out that there is a new technological development, which happened with both dinaceb and with Alar, where you could measure to a smaller percentage than you could with the prior equipment—and that led, Mr. Chairman, to the comments that I think Senator Hatch made very well this morning; this happens in FDA too—if you've got an agency that doesn't have modern equipment and they are putting out a particular standard and then all of a sudden you say, well, really, though the present standard says there is nothing left, we have found that there really is a residue left.

And, Mr. Groth, going to yours on multiple residues, that particularly becomes effective, then that product becomes suspect. And if that is issued by any laboratory in the country, private or otherwise, it goes immediately on the evening television, and regardless of what the FDA or the EPA has said, that then becomes the standard.

So I am very interested in a standard being produced. Not the one suggested by the President. I agree that that is not acceptable. And I don't say that it is risk-benefit. But there has to be a definiteness if we are going to produce a flow of food into the supermarkets because these producers—and I am going to tell you what is going to happen in the State of Washington is that the smaller growers with the types of products that are liked by the new so-called yuppie society don't grow much. They use a particular kind of pesticide that may be a little different. The chemical companies are saying to them, you aren't a big enough market, we can't take the expense of going through the regulatory system and therefore we have just decided to stop making whatever your pesticide or whatever you use is. It's called the small-pesticide problem.

I am not arguing that these pesticides should just be allowed out there, but these people at that point go out of business because they are unable to obtain this stamp of approval.

Now, I have mentioned this to the chairman and to the ranking member—not because I am not for this bill; I am going to help you pass it and I hope we pass it very quickly—but because I am deeply concerned that our food chain is going to be enormously impacted right now with the technological changes that are happening. And we need your help because we cannot grow enough—and my daughters do this all the time—biological and organic food to supply our total population. And I was glad that you mentioned changing new plants, and you mentioned tomatoes. I have grown tomatoes for 15 years and they have not grown and you cannot grow in the Washington, D.C., climate a tomato that will not get the blight. And they put one out every three years. Now, I am not critical of people that are doing it, I am just saying that we are in the long process of doing it, and you've got to help us, that represent kind of both ends of this spectrum to get this safe food on the market, because we all have children, we all have grandchildren.

I voted for the Delaney amendment in its original days when we were in the House. We had no idea what an impact this was going to have. All we were trying to say was don't put cancer-producing agents in food, and all of a sudden as the tests began to go on, we found that the Delaney amendment did away with everything. And we have never corrected it.

Now, I have gone on longer than I intended, Mr. Chairman, but I wanted to be sure that you understood my concerns, that the ranking member did. I will put the rest of my comments into the record. But I wanted you to know that there is no hostility on my part. I just would like to have us produce a product where we know, as it's starting out, it is safe, have some agency say that it is, and then know that when it's out on the market it is not going to be recalled.

And any comment you want to make, pro, con statement or otherwise, about mine, I would welcome it.

Thank you, Mr. Chairman.

Ms. HATHAWAY. Senator Adams, if I may just make a very brief comment, I think the only solution to the problem that you outlined very well is the chairman's bill, S. 722. It is the way that we are going to avert future Alars, and the only way, I think, that we can avert—I07Senator Adams. The 1 in a million standard?

Ms. HATHAWAY. That's right. By having a systematic health-based standard that does protect the least protected in our society, children and other people who eat a lot of a certain fruit or vegetable, and also that looks at cumulative risk.

If we take that approach, we are going to have some credibility restored, we are going to have growers know what the target it, what they are going to have to in fact produce and how they're going to have to produce it, and we are going to have the USDA know what pesticides are going to, over time, have to be phased out or phased down in their uses. And that way we are going to have a real agenda for food safety and predictability. And that is what the growers need, and that is what consumers need.

Senator ADAMS. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you very much.

Senator Hatch?

Senator HATCH. Thank you, Mr. Chairman.

Welcome, all of you, to the committee.

I will only take a few minutes here. I know we have one more panel to go. As I view it, the American consumers just want to know their food supply is safe. So I believe that there are two pillars which have to be constructed in order to restore consumer confidence. The first is that we have to establish a strict uniform food safety standard that is based upon some science in ensuring that our products will pose only a negligible risk of harm.

Our current law, which offers a zero risk standard, basically is no longer scientifically feasible. I don't know of any scientists who really argue for it.

Further, this Delaney paradox, as it was called by the National Academy, is working to keep safer products off the market which could replace older, less safe products which should be off the market.

Every commissioner of the Food and Drug Administration for the past 29 years has called on Congress to remove the rigidity of the Delaney clause, because scientifically we can do such a better job today. And these are scientists appointed by Presidents of both parties who recognize that we have to have workable, scientifically accurate Federal laws in order to protect the safety and health of all American consumers.

Now, the second pillar, that we have to construct, is a stronger set of enforcement laws that allow the removal of unsafe products with prudent dispatch. That is something we can't do today. Our current system requires a process which takes between 4 and 5 years—actually, as long as 8 years before a product can be suspended or canceled. And sometimes it only leads to a suspension after that length of time.

That is too long, and it is not surprising that States have undertaken efforts to protect their citizens when our Federal laws are so erratic and basically unsafe.

We need a strict and uniform food safety standard with strong enforcement tools so that we can protect our citizens in Utah as well as Massachusetts, New York, and every other State.

Now, let me just ask you a couple of questions. I take it that all three of you support Proposition 65 in California? Is that a fair statement?

Ms. BLOOM. Yes, we do.

Senator HATCH. You, Ms. Bloom?

Ms. HATHAWAY. NRDC does.

Ms. BLOOM. Our West Coast office did, yes.

Senator HATCH. That has a standard in it of 10–5.

Ms. HATHAWAY. That was one of the things we didn't support in it. Like in many packages there are things you like and things you don't like.

Senator HATCH. All right. I didn't mean to catch you with that. [Laughter.]

The CHAIRMAN. You did, though. [Laughter.]

Senator HATCH. A shameful thing, I know.

But Senator Kennedy and I are going to work out this standard and others, of course, in the Senate and the House. And I agree it's got to be a strict standard. So we are going to work it out. I just do whatever he tells me to do, anyway, as you all know. [Laughter.]

But what would you find an acceptable risk standard? What would you find that to be in the aggregate, you know, pesticide upon pesticide?

Ms. HATHAWAY. Well, the way that we look at it is that we ought to get to a point and we obviously aren't near there today but we can get there over the short term, where all of our pesticide risks amalgamated together are not posing a greater risk of cancer than 1 in a million. That is what Senator Kennedy's bill envisions, and I think that is what we have to get to.

Senator HATCH. So you would go with the 10–6 standard?

Ms. HATHAWAY. Right. But that would be the cumulative risk for the people who are most exposed.

Senator HATCH. Oh. The aggregate risk would be 10–6.

Ms. HATHAWAY. That's right.

Senator HATCH. Well, when you start talking about single risk to individuals, the Academy has recommended 10–6 on individuals.

Ms. HATHAWAY. Well, the way that the bill that the chairman has introduced operates is to say initially what you are going to do is make sure that each pesticide poses no more risk than 1 in a million, and then over time what you do is look at all the different pesticides that are used on a single commodity and make that gets down to 1 in a million, and then ultimately you look at all the different pesticides used together in the diet and make sure that's down to 1 in a million. So it's a phase-in approach, and I think that is a very sensible way to start.

We can get down to 1 in a million for most pesticides in a very short order. If in fact what growers and chemical companies have said is true, if it is true that their residue levels are far below the legal tolerance levels, then for most pesticides there will not be a significant problem going through that first hurdle. It's when you start amalgamating risks that you are going to find that there have to be significant use reductions to get to 1 in a million for the total exposure from pesticides.

Senator HATCH. I agree with Senator Kennedy. I don't think there is a much more important thing we can do in this next year or so than come up with really good food safety laws that give great protection to all consumers in America. Our present system is really terrible.

But if we get the right standards with strict enforcement, and maybe even if we do preempt with the Federal Government but allow State assistance in enforcement, we may have the answer. This may be a way of getting to where you folks are, solve some of the problems. If we don't have preemption, you're talking about a tremendous cost to consumers for no real additional benefit.

So I understand what you're driving at, and we are going to try to come up with some approach that will give more confidence across the board, and rightfully so.

Ms. HATHAWAY. Senator Hatch, I am very glad to hear that you are interested in working on this legislation, because I think it's extremely valuable.

But in response to the comment that you make about preemption, I think one thing to note is that the States really are not inclined to set different tolerance levels when they have confidence that the Federal tolerance levels make sense. So in fact I think you

are going to solve the entire problem of what the food industry has said is a crazy-quilt or a patchwork of different standards by simply getting confidence into the Federal standards.

Senator HATCH. This is what Senator Kennedy has been telling me, and I think he doesn't have to tell me because I agree with that. This matter has concerned me for a decade now, and I just think that it's very important that we all come together and come up with the most important changes in food safety that we can, because the present system is a lousy system.

And to that end I just want to compliment each of you for being participants in that process and to tell you how much we appreciate having you here today.

Ms. HATHAWAY. Thank you.

Ms. BLOOM. I would like to clarify that although Public Citizens supports S. 722, and it does have a 10–6 standard in it, we do feel that given the current state of risk assessment over at EPA and scientifically that in the case of carcinogens it is inappropriate to call 10-6 risk-acceptable. And we would favor a phase-out over some period of time of all pesticides that are associated with carcinogenic effects.

Senator HATCH. Then you would disagree with the National Academy on that particular point?

Ms. BLOOM. I don't think it's disagreeing with the Academy because in their report they said in the case of carcinogens the way to reduce the risk 100 percent is to phase out the carcinogens. And in the follow-up, the second way to reduce the risk which they suggested would indicate a 98 percent risk, was the 10–6 plus elimination of benefits.

Senator HATCH. I don't think, in all due respect, that we have any methodology of reducing a 100 percent risk. That is why the negligible risk standard makes sense. But I see what you're saying. OK.

Mr. GROTH. Senator, I would like to respond to your comments. I think you have asked exactly the right question when you say what should the aggregate acceptable risk level be. I would almost say that that is more important than the definition of what is an acceptable risk on an individual compound. It's the focus beyond getting the aggregate risk as low as possible.

Now, as to whether 1 in a million or 1 in 100,000 is the right level, this is a pure value judgment that the public is asking Congress to make for us. My perception is that most consumers really want zero risk. And we are not going to achieve zero. It's a matter of pursuing it to the extent that it is possible.

The California standard is, I think, the Proposition 65 standard, is an excellent example of the kind of experiment that can occur if the States are given some rein to act on their own, and I think we should look at this as a great experiment and see how it turns out. I don't think it's final yet, but I think they are using good science and good sense in administering that act at this point.

Senator HATCH. Thank you.

Thanks, Mr. Chairman.

The CHAIRMAN. OK.

Thank you very much.

The CHAIRMAN. We have a second panel: J.J. Vroom, who is president of the National Agricultural Chemical Association; Marlyn Jorgensen, president of the American Soybean Association; Michael Taylor, attorney, King & Spalding.

We will include all of your statements in the record and would ask if you could summarize them, please.

We will start off with Jay Vroom.

STATEMENTS OF JAY J. VROOM, PRESIDENT, NATIONAL AGRICULTURAL CHEMICALS ASSOCIATION, WASHINGTON, DC; MARLYN JORGENSEN, PRESIDENT, SOYBEAN ASSOCIATION, GARRISON, IA, ACCOMPANIED BY PAT RARE, STAFF; AND MICHAEL R. TAYLOR, ATTORNEY, KING & SPALDING, WASHINGTON, DC

Mr. VROOM. Thank you, Senator, and good morning.

We appreciate the opportunity to comment on various proposals on pesticides and food safety before you and proposed by the President as well as some concepts that are in front of the House of Representatives, and present those views on behalf of the members of the National Agricultural Chemicals Association.

We understand that we are to focus on S. 722 and two other legislative proposals, the President's plan introduced last week, and the comprehensive bill we would like to discuss also, H.R. 3292, before the House.

While all the proposals present a thoughtful approach, we submit that the same objectives can be achieved better in a different way.

We begin our comments with the important reiteration of the fact that our food supply is safe. Pesticide residues in our food within legal tolerance levels do not present a health hazard to consumers. The United States has the most varied, inexpensive, abundant and safe food supply in the entire world, and we are the envy of the rest of the world. Agricultural technology, including crop protection chemicals, and prudent management by farmers and ranchers are largely responsible for this blessing. Our view, in fact, is echoed by virtually every Federal and State agency responsible for food safety, by many health professionals, growers, and even some environmental and consumer advocates.

The question, accordingly, then is: How can we improve our food supply and management of pesticides used in food production and, even more importantly, restore U.S. consumer confidence in the safety of our food supply?

We submit that this can be done in three ways:

Number one, provide a workable, flexible approach to the current Delaney problem, by establishing the negligible risk concept into the law;

Number two, to speed up the administrative cancellation process for removing pesticides from use; and

Number three, to allow EPA sufficient time along with and in concert with the industry support and the resources that EPA needs to do the job that Congress mandated in the passage of the 1988 amendments to the Federal pesticide law.

Let me return to the three legislative proposals that I alluded to. Of these, H.R. 3292 is certainly preferable, in our view, as an approach, although in hearings last month we were unable to directly and totally support it. In our view, that bill would lead to unacceptable losses of essential technology available to farmers without a corresponding benefit to our food supply or administrative efficiency.

We have advanced several suggestions to the House Agriculture Committee for modifications of their approach, and we would be happy to share those with you as well.

The President's proposal compounds the problems that we have identified in the House Agriculture Committee bill. It adds new procedures and definitions and penalties that would only serve to further harm agricultural production with no commensurate improvement in the food safety beyond the approach taken in the House bill.

Finally, as regards S. 722, which as we all know focuses exclusively on the food and drug law, we believe that it sets unachievable deadlines for both industry and the Environmental Protection Agency, fails to consider the benefits of pesticides in important cases where they should be considered, introduces rigid and extreme assumptions in risk assessment.

NACA previously commented on S. 722 in hearings earlier this year, and we would be happy to again provide you with that detailed testimony for the record.

The most significant problems with S. 722 that we have identified include the fact that it expands the disharmony between the Federal pesticide and food and drug laws, making government's regulatory role more difficult and slowing the progress of FIFRA 1988 amendment benefits, to consumer confidence in the entire regulatory process, and importantly, the fact that the bill attempts to predict or anticipate future scientific discovery with its aggregation of risk concept that we don't believe is supported by current science.

We thank you for this opportunity and look forward to responding to your questions.

[The prepared statement of Mr. Vroom follows:]

PREPARED STATEMENT OF JAY J. VROOM

Good morning, Mr. Chairman and members of the committee. I am pleased to be here to comment on various proposals on pesticides and food safety. Specifically, I understand the focus of this hearing is on your bill, S. 722, and two other legislative proposals: President Bush's plan introduced last week and the comprehensive bill, H.R. 3292.

While all the proposals represent thoughtful approaches, we submit that the same objective can be achieved better in a different way.

We begin our comments with the reiteration of the fact that our food supply is safe. Pesticide residues in our food, within legal tolerance levels, do not present a health hazard to consumers. The United States has the most varied, inexpensive, abundant, and safe food supply in the world. Agricultural technology-- including crop protection chemicals--and prudent management by farmers and ranchers are largely responsible for this blessing. Our view is echoed by virtually every federal and state agency responsible for food safety, by health professionals, growers, and even environmental and consumer advocates.

The question, accordingly, is how we can improve our food supply and management of pesticides used in food production. We submit that this can be done in three ways:

- provide workable flexibility from the zero-risk Delaney Clause by establishing the negligible risk concept into the law;
- speed up the administrative cancellation process for removing pesticides from use; and
- allow EPA sufficient time and resources to do the job Congress demanded in recent 1988 amendments to the federal pesticide law.

Let me return now to the three legislative proposals that I alluded to. Of these, H.R. 3292 bill is preferable, although in hearings last month we were unable to support it. In our view, the bill would lead to unacceptable losses of essential ag chemicals without a corresponding benefit to food safety or administrative efficiency. We have advanced several suggestions to that Committee for modifications we believe could make their Bill workable for U.S. agriculture.

The President's proposal compounds the problems that we've identified in the Ag Committee bill. It adds new procedures, definitions and penalties that would serve to only further harm agricultural production, with no commensurate improvement in food safety.

Finally, S. 722...focusing exclusively on FFDCA...sets unachievable deadlines, fails to consider pesticide benefits, and introduces rigid and extreme assumptions in risk assessment. NACA previously commented on S. 722 in hearings earlier this year and would be happy to provide that detailed testimony again for the record. The most significant problems with S.722 we identified included the fact that it expands the disharmony between the FIFRA and FFDCA statutes, making government's regulatory role more difficult--and slowing progress of FIFRA '88 amendments benefits--and the fact that the Bill attempts to predict or anticipate future scientific discovery with its aggregation of risk concept.

Thank you, Mr. Chairman and Committee Members, for allowing me to speak on this important legislation. I stand ready to answer your questions.

The CHAIRMAN. Thank you very much.

Mr. Jorgensen?

Mr. JORGENSEN. Thank you, Senator. We appreciate the opportunity to appear before you. Accompanying me today is Pat Rare of our staff.

I am a soybean farmer from Garrison, Iowa, and president of the American Soybean Association. I am also testifying today on behalf of the American Farm Bureau Federation, the American Feed Industry Association, the National Corn Growers Association, the National Milk Producers Federation, the National Grange, the National Pork Producers Council, the Turkey Federation, and United Fresh Fruit and Vegetable Association.

Farmers are familiar with pesticide issues and are directly affected by the regulation of pesticides. In general, farmers support sound environmental production practices which balance their ability to economically use and conserve our natural resources. We use pesticides in accordance with Federally approved manufacturers instructions to produce the food and fiber that feeds our families as well as many families across the United States and indeed around the world.

We agree with the fundamental principle and premise underlying S. 722 and the administration's proposal that all pesticide chemicals, whether in raw agricultural commodities or in processed foods, should be regulated under same standard of safety. Consumers should benefit from application of a uniform standard that is not dependent on the form of the food treated with the pesticide. Despite this, we must oppose S. 722, as currently drafted, and we believe certain aspects of the President's food safety plan should also be modified.

With regard to S. 722, we have three primary concerns. First, as the bill is currently drafted, the benefits of a pesticide would not be considered in establishing a tolerance. Benefits to the consumers or to the food supply, the essential reasons for using chemicals at all, would not be taken into account in evaluating any risks of a particular pesticide.

When a substance such as a pesticide has limited undesirable consequences as well as desirable effects, both the risks and the benefits are relevant when determining whether such substance may be used and at what levels.

The President's proposal recognizes that need, and we believe that this is a general principle of risk assessment.

Second, the negligible risk standard set forth in the bill is too complex and broad to meet the goals intended by the legislation. The concept of negligible risk or risk too small to be significant is clearly appropriate in the area of pesticide regulation. However, as defined in S. 722, negligible risk would, in effect, constitute a zero risk standard. As does the President, we believe that negligible risk should be defined in a narrative fashion rather than codifying a numerical value. This will give the agency the ability to adhere to the science of today, not only today but tomorrow and 10 years from now.

Third, EPA would be given conflicting statutory charges under S. 722. While FIFRA requires EPA to consider risks and benefits in granting registration, S. 722 directs only that risks be considered.

Moreover, FIFRA 1988 requires that priority and reregistration be given to pesticides that meet certain criteria. S. 722, in contrast, would require that EPA complete within 90 days of enactment an evaluation of all existing safety data for each tolerance, determine whether exposure presents a greater than negligible risk and initiate action to modify or revoke such a tolerance.

Now, with respect to the President's food safety plan, we commend the President for his commitment to food safety and taking steps toward coordinating the food safety initiative of several agencies within the executive branch. We note that there are similarities in subsequent sections of the President's plan and H.R. 3292, introduced by Representatives de la Garza and Madigan. H.R. 3292 represents another sound approach to pesticide regulation and has been endorsed by the agricultural community.

We do have a couple of concerns with the President's proposal. First, in an effort to make it easier to suspend pesticide regulations during the period required for cancellation, the President's proposal contains a new definition of the term imminent hazard. The key aspects of this definition are not contained in either FIFRA or FFDCA. The proposed revision would thus be subject to inconsistent application and could result in precipitous suspensions that would place the U.S. food supply in jeopardy.

There are also important uncertainties about the enforcement provisions of the plan, especially in the recordkeeping requirements. For example, it is not clear how long growers would have to keep records and how these provisions would be enforced.

We have additional concerns over the inspection provisions that are contained in the proposal. The enforcement provisions of the administration's proposal presume that the growers will misuse pesticides. In doing so, the President's proposal places an undue and necessary burden upon farmers.

In conclusion, Mr. Chairman, our food supply is safe, wholesome and economical. Much of the credit in providing the safest and most abundant food supply in the world can be attributed to pesticides. Our attention should be focused on those health risks that are real, while fostering the continued availability of beneficial substances. The agricultural organizations represented by this testimony stand ready to assist you and the committee in addressing those real concerns.

Thank you, very much.

[The prepared statement of Mr. Jorgensen follows:]

PREPARED STATEMENT OF MARYLYN JORGENSEN

Good morning, Mr. Chairman and members of the Committee. I am Marlyn Jorgensen, a soybean farmer from Garrison, Iowa. Besides growing over 800 acres of soybeans, I produce corn, hay, swine, and beef cattle. I am here today as President of the American Soybean Association (ASA). ASA is a national nonprofit organization, representing U.S. soybean farmers, which seeks to increase the opportunity for U.S. soybean farmer profitability through market development, research, government relations, and trade policy programs. I appreciate this opportunity to testify on S. 722 - the Food Safety Amendments of 1989, and on the Bush Administration's Food Safety Plan.

Today I am testifying on S. 722 and the President's Food Safety Plan not only on behalf of ASA but also for the American Farm Bureau Federation, the American Feed Industry Association, the National Corn Growers Association, the National Milk Producers Federation, the National Grange, the National Pork Producers Council, the National Turkey Federation, and the United Fresh Fruit and Vegetable Association. These organizations represent a wide range of agriculture and agricultural products.

According to USDA, soybeans were the top cash income crop in 1988. In 1987, the most recent "normal" weather year, some 420,000 farmers produced 1.9 billion bushels of soybeans on 57 million acres, worth $11.8 billion. Almost half of the soybeans produced in the U.S. are consumed domestically and the remainder are exported. Exports of soybeans and soybean products, worth $7 billion last year, are vital to the United States balance of trade. The European Economic Community has traditionally been our largest regional market, and Japan buys more soybeans from U.S. farmers than any other single nation in the world. Other major foreign customers include Taiwan, the Soviet Union, South Korea, and Mexico.

ASA members, such as myself, are familiar with pesticides issues and are directly affected by the regulation of pesticides. In fact, ASA's Policies for the 1990's Task Force held 30 "listening sessions" across the soybean belt where farmers identified environmental policy as their number one concern. In general, farmers support sound environmental production practices which balance their ability to economically use and conserve our natural resources.

ASA members use pesticides in accordance with manufacturer instructions to produce soybeans and soybean products that feed their families as well as many other families across the United States and internationally. Additionally, soybean products are the major protein source for livestock and

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poultry feeds and are becoming an increasingly important component of aquacultural feeds. As both users of pesticides and consumers of pesticide-treated products, our members have an appreciation for the great contribution these chemicals make to our food and fiber supply as well as the need to use pesticides in a safe and environmentally sound manner.

A number of different pesticides are used on soybeans. Herbicides are the most widely used. Soybean farmers need these pesticides to produce an abundance of soybeans safely and economically.

By definition, pesticides are toxic chemicals used as poisons against insects, fungi, weeds, and other pests. Pesticides are used to enhance the appearance of a commodity and provide the high quality product that is expected by the American consumer. They also enable consumers to have a wide selection of produce all year long, and not merely during the growing season. Finally, pesticides are often needed to bolster nutritional food quality and safety. For example, some pesticides inhibit the growth of harmful bacteria which can have a serious adverse impact on health but are difficult to detect. In short, many of the achievements in the quality and quantity of agriculture products today may be attributed to the proper application of pesticides.

We are aware of the recent public alarm over the safety of the food supply and the particular concerns about pesticides that have been expressed in the media. As members of the

agricultural community, as well as consumers, we sympathize with these concerns. We believe, however, that this anxiety is truly unnecessary. Moreover, we are extremely concerned that some of our most important pesticides may be precipitously removed from the market without a full scientific analysis of the situation as a reaction to this crisis in confidence.

Contrary to recent press reports, existing evidence shows that our food supply is the safest in the world. Recent data from the Food and Drug Administration demonstrate that the overwhelming percentage of food contains no residues, and that most foods with residues are in compliance with established tolerance levels. There is no evidence that pesticides, when applied to food products in conformance with current regulatory standards, have caused illness or death in either children or adults.

Current risk assessment methodologies, which extrapolate animal toxicity data to human experience, are just that -- estimates based on assumptions that a chemical, when fed to laboratory animals at high levels, will result in some comparable effect in humans. Such mathematical estimates should not form the sole basis for our regulation of pesticides. Differences such as dose, source of exposure, purity of the test material, the extent of tumor occurrence, and the size of the exposed groups must be considered as well. These factors must be weighed just as we weigh the risk from auto accidents to set

safety standards and analyze the risk of health effects to set drinking water and air standards.

We commend the Committee for its efforts to review the law to guarantee the production of a safe, wholesome, and economical food supply. However, we must oppose S. 722 as it is currently drafted. We urge the Committee to consider carefully how certain changes in the law could have perhaps unintended and undesirable consequences.

Consistent Standards Should Benefit Consumers And Users

We agree with the fundamental premise underlying the Food Safety Amendments of 1989 and the Administration's proposal that all pesticide chemicals, whether in raw agricultural commodities or in processed foods, should be regulated under the same standard of safety. In this regard, both S. 722 and the President's proposal provide that all food tolerances would be established under the same section of the Federal Food, Drug, and Cosmetic Act, and not under two different standards as under present law. Consumers should benefit from application of a uniform standard that is not dependent on the form of the food treated with the pesticide.

In 1987, the National Academy of Sciences recommended that all pesticide residues be subject to consistent standards, whether in raw agricultural commodities or in processed foods, and whether covered by old or new tolerances. We applaud congressional and Administration efforts to implement this

recommendation. We have some specific concerns, however, about both S. 722 and the President's Food Safety Plan.

S. 722 - Food Safety Amendments of 1989

A. A Pesticide's Benefits Must Be Considered

As S. 722 is currently drafted, the benefits of a pesticide would not be considered in establishing a tolerance. Benefits to consumers or to the food supply, the essential reasons for using the chemical at all, would not be taken into account in evaluating any risks from use of a particular pesticide. When a substance such as a pesticide has limited undesirable consequences as well as some desirable effect, both the risks and the benefits are relevant when determining whether such substance may be used and at what levels. As earlier noted, pesticides provide numerous and varied benefits. Not only do pesticides help ensure the availability and affordability of agricultural products but they are often necessary to ensure the safety and nutritional value of many commodities. The health benefits offered by pesticides to the American consumer cannot be overlooked.

B. "Negligible Risk" Should Be More Clearly Defined Under S. 722

A further concern with S. 722 is that the negligible risk standard set forth in the bill is too complex and broad to meet the goals intended by the legislation. The concept of "negligible risk," or risks that are too small to be

significant, is clearly appropriate in the general area of pesticide regulation. However, as defined in S. 722, "negligible risk" for nonthreshold chemicals would be defined as not causing or contributing to a risk of any additional adverse health effect or an adverse health effect exceeding one in a million. For threshold risks, a margin of safety of at least 100 would be applied to a no observed effect level from animal studies to calculate an allowable human dietary level.

Additionally, the bill would provide that any adverse health effects be included in a negligible risk calculation. EPA would be required to use an overly cautious exposure estimate, and assume unrealistically that 100 percent of a food crop is treated with a particular pesticide at the tolerance level, unless other reliable data demonstrate otherwise. Finally, six years after enactment, the negligible risk standard would be applied based on the combined risk from the residue under consideration and all other residues having tolerances for the same crop.

Essentially, the net effect of the bill would be to read negligible risk as a zero risk standard -- a standard which cannot be met by products intended to protect consumers and produce from insects and fungus. Indeed, an important reason to remove pesticide tolerances completely from the reach of the Delaney Clause is to depart from an unreasonable zero risk standard for such products.

C. Available Alternatives to Currently Used Pesticides Must Be Considered Under S. 722

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires that pesticides, when used according to their label directions, perform their intended function without causing unreasonable adverse effects on man or the environment. That statute also requires that EPA consider the economic, social, and environmental costs and benefits of pesticide use in assessing whether a pesticide should be registered. EPA has already received direction to review the safety of pesticides' active ingredients registered prior to November 1, 1984, from the 1988 amendments to FIFRA (FIFRA '88).

Under FIFRA, EPA will not grant a registration for a pesticide unless all necessary food tolerances for residues have been established. As part of the reregistration requirements, EPA will reassess tolerances as the individual registrations come under review. Data required under FIFRA '88 include residue data and an assessment of dietary risk.

Under S. 722, EPA would be given conflicting statutory charges. While FIFRA requires EPA to consider risks and benefits in granting a registration, S. 722 directs that only risks be considered. FIFRA '88 requires that priority in reregistration be given to pesticides that meet certain criteria (i.e., pesticides that are used in food and result in residues, pesticides that result in residues in groundwater, edible fish, or shellfish, pesticides that result in worker

exposures, or pesticides with outstanding data requirements under the agency's regulations). S. 722, in contrast, would require that EPA complete within 90 days of enactment an evaluation of all existing safety data for each tolerance, determine whether exposure presents a greater than negligible risk, and initiate action to modify or revoke such a tolerance. If the deadlines imposed under S. 722 are intended to coincide and not conflict with FIFRA '88, then we suggest that this be explicitly stated in the statutory language of S. 722, and not left to interpretation by the agency.

As the bill is drafted, it would force EPA to divert its already scarce resources toward tolerance review, away from the previously mandated reregistration process. Registrants would be forced to evaluate, during both the tolerance and reregistration processes, whether to pursue continued regulatory approvals for a pesticide chemical. Any mandatory reevaluation of tolerances under S. 722 thus constitutes, at best, an unnecessary and redundant regulatory burden. The resulting regulatory burden on an agency already criticized for not meeting its existing deadlines tends to negate any realistic or additional contribution from the legislation.

Should FIFRA '88 not be adequate to ensure expeditious pesticide review, minor amendments to EPA's existing statutory authority, not a full scale proposal in a different statute, should be proposed. This could include, for example, specific

authorization for EPA to reevaluate tolerances and require reregistration of post-1984 pesticide registrations.

The President's Food Safety Plan

We commend President Bush for his commitment to food safety and for taking important steps toward coordinating the food safety initiatives under consideration by several agencies within the Executive Branch. We strongly support the provision in the President's proposal that would require appropriate consultation among departments within the Administration prior to issuance of cancellation and suspension orders. We also note that there are similarities in substantive sections of the President's plan and H.R. 3292 (the bill introduced by Reps. de la Garza, Madigan, and others). H.R. 3292 represents a sound approach to pesticide regulation and has been endorsed by the agricultural community. In this regard, the President's Food Safety Plan would permit consideration of the benefits of a pesticide if EPA finds that the level of human health risk is greater than negligible. We support this aspect of the President's plan.

Since the President's plan has not been put in the form of legislation, we cannot comment other than generally. The concepts listed below, however, need to be reviewed further to ensure a safe and adequate food supply.

A. The Revised Definition of "Imminent Hazard" Would Jeopardize the U.S. Food Supply

In an effort to make it easier to suspend pesticide registrations during the period required for cancellation, the President's proposal contains a new definition of the term "imminent hazard." Key aspects of this definition are unclear and are not defined under existing provisions of FIFRA or the FFDCA. For example, although the revised definition requires EPA to determine whether use of a pesticide poses a "substantial risk" or a "less than substantial but significant risk" to health or the environment, neither FIFRA nor the FFDCA contains similar standards. Moreover, the revised definition provides no criteria by which these determinations are to be made. The proposed revision thus would be subject to inconsistent application and other abuses as the agency and, no doubt, the courts attempted to refine the definition.

The proposed definition also could result in precipitous suspensions that would place the U.S. food supply in jeopardy. At a time when the public expects greater certainty in decisionmaking as well as timely decisions, legislation which is vague and subject to varying interpretation is counter-productive. In no event should suspension be permitted without adequate due process.

B. The Enforcement Provisions Are Overly Burdensome For Growers

The President's Food Safety Plan also would require private pesticide applicators, such as farmers, to keep records of their use of restricted use pesticides. Although farmers using only general use pesticides would not have to maintain records, both types of farmers would be subject to inspections.

There are substantial uncertainties about these provisions. For example, it is not clear how long growers would have to keep records and how these provisions would be enforced. The new recordkeeping requirements would be certain to add substantially to the cost of producing a crop. Growers have every incentive to use pesticides properly and in accordance with label restrictions. The enforcement provisions of the Administration's proposal presume that growers will misuse pesticides. In so doing, the proposal places an undue and unnecessary burden on farmers.

Summary

S. 722 and the President's Food Safety Plan are significant because they would require evaluation of all pesticide residues under the same risk standard, regardless of the form of the food in which they might be found. This addresses the primary concern of preeminent authorities (such as the National Academy of Sciences) that pesticides, whether marketed in raw or processed foods or under new or old

tolerances, should be governed by consistent standards. Application of the very stringent negligible risk standard proposed in S. 722, however, would effectively subject all food products to a zero risk standard which ironically is what the bill is designed to replace. Perhaps most important, the numerous benefits of pesticides must be recognized and reasonable risks accepted under S. 722. The President's proposal would do this. That plan, however, contains a vague and potentially unworkable standard for suspending pesticides pending cancellation. Finally, the enforcement provisions of the President's plan would place an undue and unnecessary burden on farmers and would substantially increase the cost of crop production.

Our food supply is safe, wholesome, and economical. Much of the credit in providing the safest and most abundant food supply in the world can be attributed to pesticides. Our attention should be focused on controlling those health risks that are real, while fostering the continued availability of beneficial substances. The agricultural organizations represented by this testimony stand ready to assist the Committee in addressing these real concerns.

Thank you for providing us with the opportunity to testify on these proposals.

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The CHAIRMAN. Mr. Taylor.

Mr. TAYLOR. Thank you, Mr. Chairman, members of the committee. I appreciate the opportunity to testify today on the critical issue of food safety. My name is Mike Taylor. I practice food and drug law in Washington with the law firm of King & Spalding. I also served on the National Academy of Sciences committee that published the report that has been referred to today entitled "Regulating Pesticides in Food: The Delaney Paradox."

I am here today, however, not as a representative of that committee or of any client, but in my individual capacity as a food safety lawyer.

The country does face a crisis in food safety regulation, but it is not a public health crisis. I do subscribe to the view that America enjoys the safest food supply in the world and that the risks associated with pesticide residues and other chemical are small, especially in relation to microbiological and other food-borne hazards.

It is, instead, a crisis of credibility and public confidence in the regulatory system. The public correctly demands a high standard of safety for food and wants to rely on the Nation's public health agencies to deliver it. With respect to pesticides, there is now a perception that the government's program is falling short. This perception is based partially on fact. Recent events have shown that it takes too long for EPA to act once it identifies a problem, and it is a fact that EPA's program for reviewing the safety of old pesticides has lagged badly.

The consequence of these problems is that too often EPA is unable to assure the public that a particular pesticide residue in food meets contemporary safety standards. In my view, EPA's problems flow from three basic structural flaws in the current statutory and institutional arrangements.

And I do want to stick up for EPA a little bit today, Mr. Chairman, because I think it ought to be clear to all of us that we are not going to solve the problem that we face, the confidence problem that we face, until EPA does have the tools and is restored in its credibility and confidence with the public.

The first structural flaw that I see is in the statutes. The statutes send EPA a very mixed signal when it comes to pesticides and food safety. FIFRA, in one portion of the Food and Drug Act, direct EPA to apply a risk-benefit standard, another section of the Food and Drug Act says apply a safety standard, and the Delaney clause says apply a zero risk standard for carcinogens at least in some cases.

It is obviously very difficult, indeed it is impossible, for EPA to do all of these things at the same time.

Second, the statutes impose procedural requirements that tie EPA's hands. Protecting the due process rights of licenseholders is a good thing and reflects important values of our society, but these values conflict with the goal of speedy decisionmaking. It is hard to have it both ways, and we should not blame EPA to the extent its slowness is caused by statutorily imposed procedures.

Third, EPA's resources for regulating pesticides are inadequate. Steps have been taken to alleviate this problem, at least with respect to the reregistration program for old pesticides, but the problem has not been solved. Among other things, EPA needs to build

the expertise and capacity to promptly evaluate new products and technologies which often provide safer alternatives to current methods of pest control.

The President's proposals respond only partially to these problems. They address the Delaney paradox by proposing a negligible risk standard, but it remains unclear whether EPA's basic mandate on pesticide residues in food would be a public health mandate, a risk-benefit mandate, or something else.

The proposals address the procedural problems more forthrightly, although it is very unclear at this point how they would work in practice. In any event, EPA will get little benefit from streamlined procedures without clear direction on the standards it should apply to pesticides in food.

Finally, the President's proposal is simply silent on providing the resources to support the kind of prompt action the public is demanding.

I applaud the committee's attention to this issue. Our agricultural economy relies on pesticides. The public demands safe and economical food. In the end, only Congress can balance the competing social values at stake in pesticide regulations and only Congress can give EPA the legal tools and resources it needs to do its job.

I also urge the committee, though, to look beyond pesticides and consider food safety more broadly. Like EPA, the Food and Drug Administration, the Nation's primary food safety agency, is saddled with the scientifically obsolete Delaney clause. Like EPA, the FDA lacks the resources to do the job we have given it.

The goal of your efforts should be a coherent national food safety policy, one that is driven by considerations of public health, recognizes the practical need for pesticides, takes full advantage of science, and is administrable.

The public demands this much, and the farmers and manufacturers who produce the Nation's food deserve it. The time seems right for Congress, working closely with the agencies, to review the system we now have and to set a course for the future.

Thank you, Mr. Chairman. I will be happy to answer questions.

[The prepared statement of Mr. Taylor follows:]

PREPARED STATEMENT OF MICHAEL R. TAYLOR

Mr. Chairman and members of the Committee, I appreciate the opportunity to testify today on the critical issue of food safety. I served on the National Academy of Sciences committee that published the report Regulating Pesticides in Food -- The Delaney Paradox. I am here today, however, not as a representative of that committee or of any client, but in my individual capacity as a food safety lawyer.

The country faces a crisis in food safety regulation, but it is not a public health crisis. I subscribe to the view that America enjoys the safest food supply in the world and that the risks associated with pesticide residues and other chemicals are small, especially in relation to microbiological and other food-borne hazards.

It is instead a crisis of credibility and public confidence in the regulatory system. The public correctly demands a high standard of safety for food and wants to rely on the Nation's public health agencies to deliver it. With respect to pesticides, there is now a perception that the government's program is falling short.

This perception is based partially on fact. Recent events have shown that it takes too long for EPA to act once it identifies a problem, and it is a fact that EPA's program for reviewing the safety of old pesticides has lagged badly. The consequence of these problems is that, too often, EPA is unable to assure the public that a particular pesticide residue in food meets contemporary safety standards.

In my view, EPA's problems flow from three basic structural flaws in the current statutory and institutional arrangements:

1. The statutes send EPA a very mixed signal when it comes to pesticides and food safety. FIFRA and one portion of the Federal Food, Drug, and Cosmetic Act ("FDC Act") direct EPA to apply a risk-benefit standard. Another section of the FDC Act says apply a "safety" standard. And the Delaney Clause says apply a zero-risk standard for carcinogens, in some cases. It is very hard for EPA to do all of these things at the same time.

2. The statutes impose procedural requirements that tie EPA's hands. Protecting the due process rights of license-holders is a good thing and reflects important values of our society, but these values conflict with the goal of speedy decisionmaking. It is hard to have it both ways, and we should not blame EPA to the extent its slowness is caused by statutorily-imposed procedures.

3. EPA's resources for regulating pesticides are inadequate. Steps have been taken to alleviate this problem, at least with respect to the re-registration program for old pesticides, but the problem has not been solved. Among other

things, EPA needs to build the expertise and capacity to promptly evaluate new products and technologies, which often provide safer alternatives to current methods of pest control.

The President's recent proposals respond only partially to these problems. They address the Delaney Paradox by proposing a negligible risk standard, but it remains unclear whether EPA's basic mandate on pesticide residues in food is a public health mandate, a risk-benefit mandate, or something else.

The proposals address the procedural problems more forthrightly, although it is very unclear at this point how they would work in practice. In any event, EPA will get little benefit from streamlined procedures without clear direction on the standard it should apply to pesticides in food.

The President's proposal is simply silent on providing the resources to support the kind of prompt action the public is demanding.

I applaud the Committee's attention to this issue. Our agricultural economy relies on pesticides. The public demands safe and economical food. In the end, only Congress can balance the competing social values at stake in pesticide regulation, and only Congress can give EPA the legal tools and resources it needs to do its job.

I also urge the Committee to look beyond pesticides and consider food safety more broadly. Like EPA, the Food and Drug Administration, the Nation's primary food safety agency, is saddled with the scientifically obsolete Delaney Clause. Like EPA, FDA lacks the resources to do the job we have given it.

The goal of your efforts should be a coherent, national food safety policy -- one that is driven by considerations of public health, recognizes the practical need for pesticides, takes full advantage of science, and is administrable. The public demands this much, and the farmers and manufacturers who produce the Nation's food deserve it. The time seems right for Congress, working closely with the agencies, to review the system we now have and set a course for the future.

I will be happy to take your questions on the specific issues addressed in the President's proposal and in the Chairman's pending legislation.

The CHAIRMAN. Thank you. Thank you very much.

Mr. Jorgensen, if we have the safest food supply in the world, what are your real concerns about the test of 1 in a million? If it is as safe as you would suggest, then I wouldn't think that you would have any problem about removing any of these chemicals.

Mr. JORGENSEN. Senator, my role as a farmer is to provide that food. You know, I am not a scientist or a chemist, and I don't know whether it's 1 in a million or whatever that case may be, I do not have that knowledge. I rely on the technology and the ability and the wisdom of Congress and the agencies to give me that rule.

The CHAIRMAN. That is very helpful. So, if the medical scientists, in terms of what they believe is essential to protect the health, say it's 1 in a million, you're prepared to sign off on it?

Mr. JORGENSEN. No, sir, I didn't say that. I said my role——

The CHAIRMAN. You did say that you are a farmer, I respect that, but you don't have the scientific know-how to make a judgment, and we all understand that. And so the conclusion would be that scientists that do have the competency to assure risk, ought to guide us. I am not a scientist either. We are generalists. You are a farmer and a specialist. We are generalists. So we have to rely on science in terms of trying to make some judgment. Now that is what I am trying to get at.

I understand that you are telling me that you can't make that judgment. We shouldn't expect you to. But if the best scientific information on health risks supports a definite negligible risk standard, I understand the bottom line would be that you would support it?

Mr. JORGENSEN. I think the key concept is that we don't think that you can codify a number because technology continues to change and how are you going to identify the number today or tomorrow or 10 years from now is going to affect my ability to produce safe food for the world.

The CHAIRMAN. Why is that? You may find that technology may make risk assessment more accurate, but if we set a standard today and better information is developed to improve the standard, shouldn't we then strengthen that standard? Technology helps to improve the precision of risk assessment. We make a bottom line. We draw the line today. You get additional scientific information which makes it more accurate. But what's wrong with that?

Mr. JORGENSEN. Well, let me look at something in terms of what you've got, you're trying to evaluate the benefit or the cost of that level. You're saying this is the level above which we should not accept risk. And I don't know if there is a level. I can't justify that any more than somebody could justify what is the risk of another person, poor person in Los Angeles or Boston dying because they can't afford a food supply.

And so I think we have that paradox that we have to look at.

The CHAIRMAN. We certainly ought to be making the judgment, whether we're going to support nutrition, WIC programs, women and infant children, food stamp programs. We authorize these programs and try to determine our interests, our priorities. You don't think that one of those priorities ought to be to establish basic health and safety scientific standards in terms of what the scientif-

ic community thinks provides for acceptable risk in terms of cancer?

Mr. JORGENSEN. Well, I don't think that we have uniformity of judgment as to what is acceptable risk. And that is the point I am trying to make, that I do not know that. I am not a scientist. I mean you have technicians who could talk about that.

The CHAIRMAN. You don't believe that the Academy of Science, which is made up of well respected scientists, is about as good as we can get? I understand you making arguments in terms of agriculture and food, saying you want some certainty, some predictability, you don't want one pesticide on and then taken off 2 weeks later.

My understanding is that many of the small farmers are ahead of many of the larger agribusinesses in these areas about the use and selection of various pesticides; I may stand corrected—but how many more cancer cases do you think we should permit under your standard? You said that the criticism with our bill is that it doesn't consider the benefits either to the consumers or to the food supply. Where do you draw the line? How many more cancers?

We had some testimony here that just in the eight pesticides, their just rough ballpark was 5,500 annually, just roughly. I mean say it's 50. How many additional cancer cases are you prepared to accept in exchange for benefits to the food supply or consumers?

Mr. JORGENSEN. Senator, we don't live in a risk-free society and——

The CHAIRMAN. Fifty-five thousand people are killed in automobile accidents each year. Don't give me that argument. I hear that every day around here. We've heard it for 28 years.

What we try to do is to reduce risk of injury, illness and death. That is why we have speed limits. That is why we have safety inspections in airlines. We don't do all the things that we should. But we try to reduce what risks we can. I just want to know from your point of view how many more cancer cases are you prepared to accept balanced against consumers' interest and the food industry's interests.

Mr. JORGENSEN. Senator, I can't make that decision because I don't have all the available information.

I think it is interesting, Dr. Harold Freeman, who is president of the American Cancer Society and director of surgery in New York's Harlem Hospital, said in USA Today on March 29 that there is a definite link between cancer and poverty and he knows that while diet patterns and health care are key considerations, access to wholesome food in the form of quality fruits and vegetables at affordable prices should also be a consideration.

So I am not in a position to make that determination, Senator.

The CHAIRMAN. Well, you are not. Significant risk comes from lead paint in older houses that kids ingest. There are many of us who are trying to do something about reducing these risks.

Mr. JORGENSEN. I applaud those efforts.

The CHAIRMAN. Yes. There are a lot of those areas, but let's return to the risks of pesticides on foods, particularly for children. I am glad you mentioned them, because the best information available demonstrates that children up to 5 are at greatest risk from

pesticide residues on foods because of their increased consumption of fruits and vegetables.

All I wanted you to know is that if you are coming in here and saying that 1 in a million isn't right because of the potential adverse impact on consumers and the food supply.

And if you're saying that this is unacceptable because it doesn't consider the benefits to consumers and food supply, and you won't give us an answer as to what you think is a tolerable risk of cancer, I think it's tough to give great weight to your testimony.

Mr. JORGENSEN. Well, Senator, my testimony did say that there ought to be a narrative definition of that.

The CHAIRMAN. What gives you confidence that a narrative definition would be fairer or give greater protection to the public health than a precise scientific number? What possible evidence is there that it would?

Mr. JORGENSEN. Well, I think the evidence that we continue to discover new knowledge is where I would base that.

The CHAIRMAN. Mr. Vroom, Mr. Taylor, I will give you a crack at it.

Mr. VROOM. Thank you, Senator.

I think it's important to go back to the precepts of risk assessment that are built into coming up to a 1 in a million or a 1 in 100,000 risk calculation. In getting there, calculating pesticide risk as science does at EPA, there are a number of 100-fold, 10-fold risk levels already built in before they even begin to calculate those multiple risk exposures.

And they are also based on the tolerance levels of residues, and we know that in the real world the vast majority of the FDA samplings of the food in the food supply and also by the States—the California Department of Food and Agriculture has a very exhaustive residue analysis system—that we see real-world levels of exposure way below those tolerance levels.

So there are many-fold of protection levels between us and these theoretical risk assessment numbers. And that would be one important consideration to take into account as you consider the remarks that we have made and that Mr. Jorgensen has made here.

The CHAIRMAN. Mr. Taylor?

Mr. TAYLOR. If I may make a comment on the concept of the 10-6, the 1 in 1 million risk, as the Food and Drug Administration evaluates the safety of food additives and color additives and constituents of those materials under a 1 in a million standard, the agency expresses its conclusion when it arrives at a number that is at or below 1 in a million is a judgment that the material is safe.

And the agency does that because it recognizes that contrary, I guess, to the premise of your inquiry about the number of cancer deaths, the science is not precise in the sense of yielding when it produces that 1 in a million estimate, a prediction or a statement of actuarial risk. As you know, it is an upper-bound limit leading the agency to draw the conclusion that a 1 in a million risk arrived at this way is the functional equivalent of no risk at all.

I think one reason why it would be undesirable to codify 1 in a million in the statute is that there may be circumstances both where the science would tell us the risk below a quantitative risk arrived at just based on the statistical extrapolation, the science

would tell us that a risk that is somewhat greater than a calculated risk that is somewhat greater than 1 in a million is not a safety problem, whereas a risk that is calculated slightly below 1 in a million might be a safety problem based on all of the evidence, the biological qualitative evidence we have about the material.

I think what it really comes down to, if you want to rely upon the 1 in a million standard as a benchmark, is your willingness to ultimately rely on the scientific judgment of public health officials and scientists in the agencies who have credibility and who have the public's confidence.

And that is the basis upon which I would advocate not codifying a number in the statute but recognizing the 1 in a million as a good quantitative rule of thumb but that does not end the scientific analysis of whether the particular exposure is safe.

The CHAIRMAN. That is a helpful answer. The question is, given the range and accuracy of science we are going to make progress in understanding risk assessment and the risk of cancer from pesticide residues, and hopefully will get a cure for cancer. Progress will be made in the future, and we look forward to these alterations and changes. Institutionally we don't do nearly what we should.

Let me say very sincerely, having given you a good sense of where I am coming from, this panel here can be enormously helpful to us. You have a lot of expertise, and we are going to need it as we go through this. And we invite you to help us and guide us. This legislation would get through a lot quicker, and be a lot more responsive, if we are all able to get aboard. Maybe we can, maybe we can't, but we are going to make a first-class effort to do so. We would like to have your support. Maybe it's there. As I say, I hope it would be.

So we have some distance to go for it, but we are prepared to seek areas of common ground. I say that very sincerely, so we hope you will keep in touch with us. You have a good feel for at least some of the different viewpoints, and we would like to ask for your active participation.

I am sure that you will be called on by the membership and the staffs, and we certainly welcome your input.

Mr. JORGENSEN. We appreciate that, and we would be very glad to do that.

The CHAIRMAN. Fine.

And if there are other comments that you want to make because we didn't have a chance to hear out everybody on some of these matters, we will make that a part of the record.

[Additional statements and material submitted for the record follow:]

United Fresh Fruit and Vegetable Association

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PREPARED STATEMENT OF THE UNITED FRESH FRUIT AND VEGETABLE ASSOCIATION

The United Fresh Fruit and Vegetable Association is the national trade association representing the fresh produce industry. Our 2,500 member companies handle 80 percent of the fresh fruit and vegetables commercially marketed in the United States.

The produce industry is very much aware of the on-going debate and consumer concern regarding the safety of our products. After apples and Alar, followed by cyanide in Chilean grapes, we can only hope that Andy Warhol was right, and that the produce industry has had its quarter hour in the limelight. As you well know, this fear of pesticides is generated for the most part by the fear of cancer. The public's fear of cancer is being inflamed at the very time in our history when we are seeing at least level incidence rates, and in some cases an actual decrease in the frequency of most major types of cancer. The scientific community generally agrees that reductions in the incidences of some cancers (such as colon cancer) reflect a clear correlation with the increased consumption of low fat, high fiber foods, specifically fresh fruits and vegetables.

United and its members want legislation and subsequent regulations improved and modernized in order to take advantage of the best contemporary science to assure public safety and enhance consumer confidence in the food supply. However, we strongly believe that the many questions regarding risk and exposure must be answered by scientists and public health specialists empowered by law to follow the dictates of good science and good sense. Unfortunately, we must conclude that the proposed amendments to the Federal Food, Drug and Cosmetic Act (FD&C Act) are driven by unjustified and unwise chemophobia rather than science.

The bill S.722, the Food Safety Amendments of 1989, does recognize recent advances in scientific technology that have made the "zero risk" language of the Delaney Clause virtually unworkable.

This legislation, as introduced by Chairman Kennedy, would seem to recognize that pesticides provide some benefits by allowing the use of those that are potential carcinogens so long as they present only a negligible risk, but the legislation then disallows any other consideration of benefits. Although the Environmental Protection Agency would have more flexibility if negligible risk were not defined by statute, United can support legislation defining negligible risk as one-in-a-million. Such a definition means that there is a potential increase in the cancer risk of one additional case in one million people in a lifetime. We cannot support the way the bill requires the Administrator to determine if the risk is negligible.

Although we cannot support S.722 as currently drafted, United will enthusiastically work with members of this committee or any other to write new legislation. We are well aware that even with a different bill such as H.R. 3292 and the Administration's proposal, our growers face the loss of some pesticides. We strongly believe that tough and credible legislation must be enacted in order to ensure consumer confidence.

This legislation, as drafted, would create chaos for production agriculture. The EPA is told how to determine whether a given chemical passes the negligible risk criteria. In all situations, the proverbial "worst case" scenario is to be used in assigning risk. In calculating dietary exposure to pesticide residues in or on raw agricultural commodities or processed foods, the EPA must consider the level of exposure to be that which would occur if the pesticide were used on all the commodities and foods for which there is a tolerance for that pesticide. The chemical residues would be considered to be at the highest legal levels, and it would be assumed a person consumed those levels of the pesticide on a daily basis over a lifetime.

As a safety buffer, the EPA already uses a worst case scenario. Currently, however, the EPA considers the benefits that would occur if the pesticide were allowed on the market, or the benefits that would be lost from removal of the pesticide from the market place. The Kennedy bill does not allow the consideration of any benefits. The produce industry believes that pesticides have proven highly beneficial to consumers by providing an abundant, wholesome, nutritious and affordable food supply. We are living longer, healthier lives than ever before in our history, and our improved diets deserve much of the credit.

In the report, "Diet and Health -- Implications for Reducing Chronic Disease Risk", released earlier this year by the National Academy of Sciences the point is made that we are living longer which "suggests that our society as a whole is not facing a health crisis posed by environmental agents." The report also recommends that each person, "Every day eat five or more servings of a combination of vegetables and fruits..." The NAS report even took into account the use of agricultural chemicals in its section, "Recommendations on Diet, Chronic Diseases, and Health". On page 28-44 the NAS discusses pesticide residues on vegetables and fruits. Although the Academy recognized that "Increased consumption of vegetables and fruits can be expected to result in increased ingestion of residues of herbicides and pesticides used in agriculture...the potential small increased risk of these somewhat uncommon tumors that might result from increased exposures in the general population would be greatly outweighed by the potential benefits to be expected from greater fruit and vegetable consumption."

In April, the Institute of Food Technologists released the report, "Assessing the Optimal System for Ensuring Food Safety: A Scientific Consensus." This report was endorsed by fourteen societies representing over 100,000 scientists including toxicologists and food scientists and was delivered to members of Congress. Each member of this committee should read the complete report. However, we would like to quote one short paragraph. "The public's perception of pesticide residues and their effect on the safety of the food supply differs considerably from the facts. Consumer surveys suggest that pesticide residues in foods are a high priority issue for the general public. However, current scientific evidence indicates that any health risk associated with pesticide residues is negligible and is orders of magnitude less than that of foodborne diseases such as Salmonella and Shigella."

We have two scientific documents that say pesticides do not pose a significant health risk. However, we are discussing legislation designed to further reduce any possible health risk from consumption of foods containing pesticide residues. Once again, we must urge this committee to be guided by science and the recognition that there are dietary benefits from the use of pesticides, not just economic.

We cannot be certain which pesticides we will lose under this proposed legislation. However, the way this bill restructures the tolerance setting procedures, we believe that we could lose most of the 60 plus food use chemicals that are known animal carcinogens. This is a very large percentage of the 300 food use pesticides.

The inflexible guidelines for establishing tolerances may very well lead to the cancelation of most of these pesticides. Within 120 days of enactment, the EPA must determine whether a chemical may present more than the negligible risk and issue a notice. If the notice is for a chemical with one or more tolerances, then within two years the risk for each tolerance must not exceed the negligible risk standard. Within four years, the risk from all residues of the pesticide on all crops must not exceed the negligible risk standard. Within six years from the original notice, the risk from all residues that have a tolerance for the specific commodity must not, in total, exceed the negligible risk standard. We believe that the accelerated reevaluation of current tolerances required by this bill establishes an unrealistic time schedule in conflict with the new FIFRA amendments enacted in 1988.

It is not true that pesticides are not needed and are only used for cosmetic purposes or to increase industry profits. This country alone loses $20 billion worth of food crops annually to pests at the current level of chemical use. Worldwide, approximately one third of all food crops are lost to pests before they can reach anyone's dish or bowl. Pesticides are necessary, yet their use must be carefully controlled and monitored. In this country, most consumers would like as few added chemicals in their food as possible. Pesticides do contribute to some degree to environmental degradation, although to what extent is unclear--certainly less than ocean dumping of waste, or tropical deforestation, or depletion of the ozone layer. And, of course, pesticides are very expensive and represent one of the most significant input costs faced by farmers.

For these reasons and others, United long ago adopted a policy of vigorously exploring alternative means of production including integrated pest management, low-input sustainable agriculture, and simple chemical use reductions where and when feasible. The produce industry, like others, is market driven, and therefore very sensitive to consumer concerns.

Our Board of Directors has formed an Organic Produce Task Force. At their first meeting in early May, several proponents of organic farming were present and they will continue to be an active part of the meetings. United supports a federal definition of organic production in order to lend consistency and prevent consumer confusion. Presently, there are some 18 states that have a law or regulation defining organic, and they generally differ. But let me emphasize, organic farming may actually benefit from pesticides.

Organic produce may be grown without the use of man-made pesticides, however, in areas heavily farmed and cultivated there are more pests than where there is little farming. Therefore, organic farmers in the heavily farmed areas do benefit from their neighbors conventional farming methods that reduces the number of pests in the area. And most plants have naturally occurring pesticides to help them combat their enemies. We are working to ensure that the consumer has a choice, any time of the year. But to do that, we must have an arsenal of safe tools. We cannot continue such high quality, abundant supplies of fresh fruit and vegetables without the judicious use of pesticides.

We believe that the produce industry has responded positively to cor concerns. Farmers are already voluntarily reducing the amou pesticides used. Many now apply pesticides when there is a pest p rather than an early application before the pest is actually infestin crop.

We are enthusiastic about working with this committee to develop legislation that will strengthen our laws and regulations governing food safety and the use of chemicals. However, we believe that S.722 creates more problems than it solves. We have grave concern that this bill would cripple the world's most effective agricultural production system, without appreciably improving human health now or in the future.

We thank you for this opportunity to express our views, and look forward to working with each of you on strengthening our food safety laws.

National Association of Wheat Growers
415 Second Street, N.E., Suite 300, Washington, D.C. 20002, (202) 547-7800

November 8, 1989

The Honorable Edward M. Kennedy
Chairman
Committee on Labor and Human Resources
United States Senate
Washington, D.C.

Dear Mr. Chairman:

I would like to ask that the enclosed letter addressed to House Agriculture Committee chairman Kika de la Garza and signed by 33 agricultural organizations be included in the committee's food safety legislation hearing record. The letter is an expression of support for H.R. 3292, the Food Safety Assurance Act of 1989.

Thank you very much.

~~Sincerely,~~

Reggie Wyckoff
President

October 18, 1989

The Honorable E. de la Garza
Chairman
Committee on Agriculture
US House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

We are writing to express our support for H.R. 3292, the Food Safety Assurance Act of 1989.

The bill is designed to improve the federal regulation of pesticides, and will, we believe, accomplish the following:

— substantially strengthen and modernize our food safety laws;

— remove perceived statutory impediments to rapid, rational action on problem pesticides; and

— reemphasize the importance of ensuring that our Nation continues to enjoy a safe, abundant, and wholesome food supply.

The members of our organizations produce, process and distribute most of the nation's food, and for that reason public confidence in the safety of our food is of utmost importance to us. Any perception by the public that the federal food safety system is flawed will inexorably lead to widespread concerns. We support H.R. 3292 because we think its enactment will make the federal regulatory system stronger while recognizing that prudent pesticide use often can yield dietary benefits to food consumers that more than offset any associated risks.

Our support for the bill was not lightly arrived at. We think that current law, while concededly in need of updating in some areas, has yielded a national food supply that is unquestionably safe. Moreover, some provisions of the bill will tend to lessen the availability of pesticides that are important to food production. Nonetheless, after assessing the situation, we believe that the bill deserves support because of its balanced and careful approach.

The Environmental Protection Agency (EPA) regulates pesticides under two statutes. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) governs the sale and use of pesticides. A pesticide product cannot be lawfully sold unless it has been registered by EPA, and cannot be lawfully used in a manner that is inconsistent with the labeling for the pesticide that was approved by EPA as part of its registration. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA sets the "tolerances" (allowable levels) for pesticide residues in or on foods. Food bearing residues that exceed a tolerance level is deemed adulterated and is subject to seizure. H.R. 3292 would make important strengthening changes in both laws.

Streamlining the FIFRA Process

Under current law, EPA uses an informal proceeding called "special review" to gather facts about a problem pesticide and to develop a regulatory position. If EPA decides that registration of a product should be canceled or that limitations should be placed on how it is used, that action is taken following the completion of "special review" and, for some products, a formal adjudicatory hearing. H.R. 3292 would streamline this process and would therefore speed up decision-making.

Prompt Reassessment of Risks from Registered Pesticides

H.R. 3292 also would require that as soon as EPA has sufficient toxicity and dietary exposure data on a pesticide chemical, it must expeditiously reassess the dietary risk, publish its findings, and take whatever action, if any, is warranted under FIFRA and FFDCA to ensure that the pesticide residues on food satisfy the safety criteria of the two laws. In particular, this new provision will produce prompt regulatory responses to new information submitted to EPA under the reregistration requirements imposed on old pesticides by the amendments to FIFRA enacted in 1988. This requirement will result in the reevaluation of dietary risks from pesticides on the quickest schedule that is practicable.

Harmonizing Statutory Food Safety Criteria

The Food Safety Assurance Act would remove inconsistencies in the criteria for setting or reviewing tolerances for pesticide residues under the FFDCA. Current law wisely allows the EPA to balance the public health benefits that result from pesticide use against any dietary risks from the pesticide's residues when considering what tolerance level should be set for a raw agricultural commodity. However, in some cases, the "Delaney clause" in the FFDCA (enacted in 1958) precludes such balancing when EPA is evaluating tolerances for processed food made from such a raw commodity. Current law also tends to discriminate against the introduction of new pesticides, even those that might be safer than those that would be replaced. The National Academy of Sciences has criticized this "Delaney Paradox" in a 1987 report that urged adoption of a uniform, nondiscriminatory standard.

H.R. 3292 would remove these statutory contradictions. A uniform set of criteria would apply for both new and old pesticides, and for both raw commodities and processed foods. The bill would go on to provide sensible criteria for setting or reassessing tolerances, keyed to the protection of public health. A tolerance would be approvable if it would result in no more than a negligible risk, or if any dietary risk would be outweighed by benefits to the food consumer from pesticide use. Such benefits could include avoidance of risk from food-borne toxic microorganisms or increased wholesomeness, availability, or affordability of food.

Without question, the federal laws should provide consistent standards governing the use of pesticides in food production and governing the residues on food that result from such use. These standards should take into account the important benefits to food consumers that pesticide use can provide. Indeed, if the FFDCA amendments in H.R. 3292 are adopted, we would also urge that the FIFRA standard for cancelling or modifying registrations be amended to provide that a pesticide could be sold or used in food production only if the resulting residues on food would satisfy the new FFDCA criteria for protection of the public health. This would achieve ultimate harmonization of the federal food safety laws.

National Uniformity

It would also be helpful to increase the level of consistency between federal and state food safety regulation. Food is marketed on a national basis, and both producers and consumers benefit significantly from a consistent set of standards that allow the efficient distribution of a product throughout the country.

States traditionally have played an important role in food safety regulation, and H.R. 3292 recognizes that special local conditions may warrant setting tolerance limits that vary from federal levels. In other cases where the data on the pesticide are incomplete or where the federal government has not performed a modern assessment of the pesticide's risks, the legislation also recognizes that a different tolerance may be warranted, even though different state tolerances will cause some disruption of interstate commerce.

However, if the data base supporting a particular food-production use of a pesticide has been found to satisfy all current requirements, if the public has had an opportunity to present information and comments on the appropriate tolerance levels in rulemaking proceedings, and if EPA, after assessing the data and comments, has concluded that a particular tolerance level is appropriate and adequate to protect the public health under the new FFDCA standards in the bill, a strong presumption should arise against the authority of state or local governments to impose different tolerance levels. H.R. 3292 would provide that in these carefully limited situations, a federal determination regarding allowable residue levels could be altered by a state only if the state showed, in a petition proceeding, that the federal standard was inadequate to protect the health of certain food consumers within the petitioning state.

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Increased Monitoring for Residues and Gathering of Use Data

Importantly, the legislation authorizes additional resources for increased pesticide residue monitoring on imported and domestic food. It also calls for the Secretary of Agriculture, by use of biennial surveys, to collect data on the use of pesticides for all the major crops and all other crops of dietary significance. Such data will help ensure a more precise procedure for measuring real levels of dietary risk and setting residue tolerances. We would also suggest that additional resources should be allocated to USDA to strengthen its analytical capabilities in regard to pesticide regulation.

In conclusion, we are confident that H.R. 3292 will significantly improve and speed the pesticide regulatory process, and that by strengthening EPA's authorities it responds to public concerns related to food safety. We believe H.R. 3292 approaches the food safety issue in a comprehensive and balanced manner. It tightens regulations for the marketing and use of pesticides, while establishing valid standards for ensuring the safety of fresh and processed foods consumed by the public.

Sincerely,

Alabama Farmers Federation
American Feed Industry Association
American Oat Association
American Society of Farm Managers and Rural Appraisers
American Soybean Association
American Sugarbeet Growers Association
American Sugar Cane League
Beet Sugar Development Foundation
Florida Sugar Cane League
Georgia Peanut Commission
Hawaiian Sugar Planters Association
National-American Wholesale Grocers' Association
National Association of Wheat Growers
National Barley Growers Association
National Cattlemen's Association
National Corn Growers Association
National Cotton Council
National Council of Farmer Cooperatives
National Food Processors Association
National Grain and Feed Association
National Grain Trade Council
National Grange
National Milk Producers Federation
National Pork Producers Council
National Sunflower Association
North American Export Grain Association
Oregonians for Food and Shelter
Rio Grande Valley Sugar Growers
Rice Millers' Association
United Egg Association
United Egg Producers
U.S. Rice Producers Legislative Group
Women Involved in Farm Economics

The CHAIRMAN. The committee stands adjourned.
[Whereupon, at 1:10 p.m., the committee was adjourned.]

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